

Exhibit F

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF WEST VIRGINIA
3 AT CHARLESTON

4 IN RE: ETHICON, INC., Master File No. 2:12-MD-02327
5 PELVIC REPAIR SYSTEM MDL 2327
6 PRODUCTS LIABILITY JOSEPH R. GOODWIN
7 LITIGATION U.S. DISTRICT JUDGE

8 *****

9 ORAL DEPOSITION OF ANNE HOLLAND WILSON

10 MARCH 22, 2016

11 *****

12 THIS DOCUMENT RELATES TO THE
13 FOLLOWING CASES IN WAVE 1 OF MDL 200:

14 Marty Babcock v. Ethicon, Inc., et al.
15 Civil Action No. 2:12-cv-10152

16 Daphne Barker, et al. v. Ethicon, Inc., et al.

17 Civil Action No. 2:12-cv-00899

18 Bonnie Blake, et al. v. Ethicon, Inc., et al.

19 Civil Action No. 2:12-cv-00995

20 Sharon Boggs, et al. v. Ethicon, Inc., et al.

21 Civil Action No. 2:12-cv-00368

22 Myra Byrd, et al. v. Ethicon, Inc., et al.

23 Civil Action No. 2:12-cv-00748

24 Angela Coleman, et al. v. Ethicon, Inc., et al.

Civil Action No. 2:12-cv-01267

Constance Diano, et al. v. Ethicon, Inc., et al.

Civil Action No. 2:12-cv-01145

Dina Destefano-Raston, et al. v. Ethicon, Inc., et al.

Civil Action No. 2:12-cv-01299

Monica Freitas, et al. v. Ethicon, Inc., et al.

Civil Action No. 2:12-cv-01146

Rose Gomez, et al. v. Ethicon, Inc., et al.

Civil Action No. 2:12-cv-00344

1 Dawna Hankins v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00369

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Donna Hankins, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01011

3

Mary Hendrix, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00595

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Mary Holzerland, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00875

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Myndal Johnson v. Ethicon, Inc., et al.
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Wilma Johnson v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00809

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Margaret Kirkpatrick v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00746

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Paula Kriz, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00938

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14

Cheryl Lankston v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00755

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Deborah Lozano, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-0347

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Angela Morrison, et al. v. Ethicon, Inc., et al.
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Miranda Patterson v. Ethicon, Inc., et al.
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Patti Ann Phelps, et al. v. Ethicon, Inc., et al.
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Jennifer Reyes, et al. v. Ethicon, Inc., et al.
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1 Denise Sacchetti v. Ethicon, Inc., et al.
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Stacy Shultis v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00654

3 Jennifer Sikes v. Ethicon, Inc., et al.
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Carrie Smith v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-0258

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Civil Action No. 2:12-cv-01149

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Krystal Teasley v. Ethicon, Inc., et al.
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9 Lisa Thompson, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01199

11

Roberta Warmack, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01150

12 Laura Waynick, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01151

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ORAL DEPOSITION OF
ANNE HOLLAND WILSON
MARCH 22, 2016

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19 ORAL DEPOSITION of ANNE HOLLAND WILSON,
produced as a witness at the instance of the
20 Defendants, and duly sworn, was taken in the
above-styled and numbered cause on March 22, 2016, from
21 10:00 a.m. to 1:29 p.m., before Kerrienne L. Bond, CSR
in and for the State of Texas, reported by machine
22 shorthand, at the offices of Fibich, Leebron, Copeland,
Briggs & Josephson, 1150 Bissonnet Street, Houston,
23 Texas, pursuant to the Federal Rules of Civil Procedure
and stipulations of counsel as set out herein or
24 attached hereto.

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1 (Marked Wilson Exhibit Nos. 1 - 7.)

2 ANNE HOLLAND WILSON,

3 having been first duly sworn, testified as follows:

4 E X A M I N A T I O N

5 BY MR. DAVIS:

6 Q. Good morning, Ms. Wilson. Would you state
7 your full name for the record, please?

8 A. Anne Holland Wilson.

9 Q. Ms. Wilson, we've met. I'm Paul Davis. I'll
10 be asking you some questions today. We'll get started.

11 I've handed you some premarked exhibits,
12 1 through 7. Could you take a look at those? I think
13 the first one is the notice of deposition. Are you
14 familiar with it?

15 A. I've browsed it.

16 Q. And we've requested some documents just to
17 bring with you. Can you just give us an overview of
18 what, if anything, you brought with you today?

19 A. I believe there's a copy of each of my
20 reports --

21 Q. Okay. Anything --

22 A. -- that are clean copies. They're in the
23 binder there.

24 (Marked Wilson Exhibit Nos. 8 - 10.)

1 Q. And I know that Ed has provided me -- I'll go
2 ahead and give them to you -- Exhibits 8, 9, and 10.

3 A. Those are financial data on how much has been
4 invoiced and paid, as well as a rate sheet, since the
5 initiation last July.

6 Q. Okay. And I know that we're waiting on a
7 couple more pages to get copied for us. Can you just
8 give me a brief description of what those two pages are?

9 A. Yes. Those are some drafts, some notes I
10 took, as far as the standards in place, 1345, the
11 quality system and risk standards. Those are my notes,
12 as far as the dates.

13 Q. I'll wait till we get those back to ask you a
14 couple more questions about that.

15 Can you confirm that Exhibit 2 is a copy
16 of your TVTR report?

17 MR. WALLACE: For Wave 1?

18 MR. DAVIS: I'm sorry? For Wave 1 cases,
19 yeah. Thanks, Ed.

20 A. Yes, the date is correct.

21 Q. (BY MR. DAVIS) And can you confirm that
22 Exhibit 3 is a copy of your TVTO report for the Wave 1
23 cases?

24 A. Yes.

1 Q. And can you confirm that Exhibit 4 is a copy
2 of your TVTS report for the Wave 1 cases?

3 A. Yes.

4 Q. And am I correct that you had the same three
5 exhibits attached to each one of those three reports?

6 A. I'd have to look. I know --

7 Q. If you need to go off the record and pull out
8 your own copy to confirm --

9 A. No, no, I don't need to do that. I just want
10 to check that they all say the same. There may be -- I
11 mean, this "Facts and Data Considered," I'm not sure I
12 have all of -- if they were separated by report or were
13 all put together as one. That's --

14 Q. I mean, I'll just represent to you that I
15 tried -- I'm not saying I did a perfect job, but I tried
16 to put them side by side and look to see if they looked
17 the same. They looked the same to me; but if you don't
18 know, that's --

19 THE WITNESS: Do you know if the facts
20 were all together or separated by product?

21 MR. WALLACE: I mean, that's something --

22 A. That's one thing I can't remember.

23 Q. (BY MR. DAVIS) Okay. Well --

24 A. But, otherwise, yes, they are --

1 Q. Let me just --

2 A. Other than that one question I have, they are
3 all the same.

4 Q. Okay. For instance, look at Exhibit No. 5.
5 Is that -- is that your CV?

6 A. Yes, it is.

7 Q. Did you use the same CV for all three reports?

8 A. I believe so.

9 Q. Is that your current CV -- or is that CV
10 current?

11 A. Yes.

12 Q. Okay. And if you'd look at Exhibit No. 6 for
13 a second, can you tell me what Exhibit 6 is?

14 A. This is like our -- it's actually from
15 ISO 14971.

16 Q. Well --

17 A. This is very -- you can hardly read it. It's
18 a figure from that -- that standard.

19 Q. Is it fair to say that Exhibit 6 was labeled
20 as Exhibit 2 to each of your three reports?

21 A. I believe so.

22 Q. Okay. And if you would for a moment, look at
23 Exhibit 7. Can you tell me what Exhibit 7 is?

24 A. "Facts and Data Considered."

1 Q. Okay. So that would be a list of the facts
2 and data that you considered?

3 A. Yes, it is.

4 (Marked Wilson Exhibit No. 11.)

5 Q. (BY MR. DAVIS) Okay. Now let me hand you
6 Exhibit 11 and see if you can just tell us formally for
7 the record: What is Exhibit 11?

8 A. It's a draft that has listed, on one column,
9 all of the standards that are used in the guidances; and
10 then it also lists the dates that they were released and
11 put into effect.

12 Q. Okay. And you called Exhibit 11 a draft. Is
13 that -- I mean, usually, the word "draft" means, to me,
14 that it may not be -- it may have some errors in it or
15 it may not be complete or -- well, what does that mean
16 to you in this case?

17 A. This is a working document. This is just what
18 I worked on and what I worked from.

19 Q. Okay. Is it your belief that the information
20 shown on here is accurate?

21 A. Yes.

22 Q. Okay. Basically, it would be fair to
23 summarize it -- and you've got a list of various
24 standards, and you've got release dates and

1 implementation dates and end dates?

2 A. Correct.

3 Q. Okay. And what's the difference between a
4 release date and an implementation date?

5 A. That's notated on the bottom of the first
6 page. You can see that "Release Date" says "DAV,"
7 and the date -- "DAV" means "date of availability."
8 That's when the text was actually published, versus the
9 DOP. That's the implementation date. And that was
10 really when the date that the -- it has to be -- it says
11 right here it has to be implemented. So that's
12 basically when it starts to be used.

13 Q. Okay. And --

14 A. And then the --

15 Q. I'm sorry. Go ahead.

16 A. -- next column is when it's withdrawn or
17 superseded.

18 Q. Okay. When you say the implementation date is
19 the date that it -- a standard has to be used, who made
20 that decision?

21 A. I mean, often, there's a grace period. You
22 know, somethings's published; and it gives the industry
23 time to be prepared for implementation. So, many times,
24 these guidances or standards are put out there and say,

1 "Okay. We're going to publish in 2003, but we're not
2 going to implement until 2006."

3 Q. Okay.

4 A. So that means everyone has to be ready,
5 prepared, and all changes have to be made by then.

6 Q. And is it fair to say that all of these
7 standards on Exhibit 11 relate in some form or fashion
8 to the subject matter of quality systems for medical
9 devices?

10 A. All of these on the first page relate to risk
11 management. So --

12 Q. Okay. Isn't -- maybe I'm incorrect. Isn't
13 risk management a part of a quality system?

14 A. Right. But more specifically, I mean, there
15 is a second page which is quality systems. That's why
16 I'm answering like that.

17 Q. Okay. So --

18 A. So you have your quality system standards on
19 one page; and then you have a distinct set of risk
20 procedures or, you know, guidance documents and
21 standards on another page.

22 Q. May I see your copy of Exhibit 11 just for a
23 second?

24 A. Actually, I have three of the same thing.

1 Q. Oh, they were handed to me this way. I think
2 I see --

3 A. Ah, this is in error.

4 Q. -- what happened. Okay. Well, let's try to
5 correct it. I think what happened is this --

6 MR. WALLACE: Why don't we work off of
7 this?

8 THE WITNESS: Yeah, if we could. This
9 would be much better for my eyes, too.

10 Q. (BY MR. DAVIS) Okay. Well -- but let's also
11 try to make the exhibit correct. What happened is we
12 got three copies made, and they apparently handed them
13 to us as three of the same thing and then three of the
14 same thing; so you were looking at one page, and I was
15 looking at the other. So let me try to see if we can
16 correct that.

17 Let me hand you back Exhibit 11. Can you
18 tell me if Exhibit 11, as I'm now handing it to you, is
19 the complete two-page list of standards that you brought
20 with you today?

21 A. Yes.

22 Q. Okay. And the -- one page of the standards
23 lists risk management standards; is that correct?

24 A. Yes.

1 Q. And just so the record will be clear, is that
2 the page that has -- the first entry on it, under the
3 column "Standard," the listing "GHTF/SG3/N15R8"?

4 A. Yeah.

5 MR. WALLACE: Objection to form.

6 A. That is actually not a standard. It's a
7 guidance. But it does start like that.

8 Q. (BY MR. DAVIS) Okay.

9 A. So this is not just standards, and nor do they
10 all apply to these, because they're not all within this
11 time frame. It's just a general listing that I used for
12 my reference.

13 Q. Okay. Other than -- you said the first entry
14 on the page I just read to you is a guidance. Are
15 the other entries on that page -- are they --
16 do they relate to risk management standards?

17 A. They do relate to risk managements, and
18 they'll all guidance to industry on how to perform
19 medical device risk analysis.

20 Q. Okay. And then let's look at the other page
21 of Exhibit 11. Is it fair to say the first entry on
22 that page is a standard ISO 13485:1996?

23 A. Yes.

24 Q. Okay. How would you characterize all of the

1 standards listed on this page?

2 A. I would characterize these as a variety of
3 quality management system guidelines that tell the
4 fundamental requirements for any medical device.

5 Q. Okay. Now, if we try to look at the big
6 picture for a second, is it fair -- would it be fair to
7 say that your three opinions relate to -- or I'm
8 sorry -- your three reports, rather. Pardon me.

9 Would it be fair to say that your three
10 reports relate to a discussion of Ethicon's quality
11 system and its risk management program?

12 A. No, I can't really say anything about the
13 entire quality system because I only looked at a small
14 part of the quality system, but -- the part relating to
15 design controls and risk management.

16 Q. Okay. Now, these standards that you looked at
17 and evaluated in this case, as applicable to Ethicon, do
18 they relate to the concept of safety of medical devices?

19 MR. WALLACE: Objection to form.

20 A. Safety is a key element of risk management.

21 Q. (BY MR. DAVIS) Okay. And would it be fair to
22 say that your reports express opinions to the effect
23 that Ethicon did not comply with industry standards that
24 relate to safety of medical devices?

1 MR. WALLACE: Objection to form.

2 A. My opinions were that -- that, in general,
3 Ethicon did not follow their own procedures, nor did
4 they follow the fundamental requirements for a medical
5 device manufacturer for risk management and design
6 control.

7 Q. (BY MR. DAVIS) Well, you're not actually
8 opining, are you, that the TVT, TVTO, and TVTS devices
9 are not safe, are you?

10 MR. WALLACE: Objection to form. It's a
11 double negative.

12 Q. (BY MR. DAVIS) Well, are you testifying -- or
13 strike that.

14 Did you form opinions in this case that
15 TVT, TVTO, or TVTS was not a safe device?

16 MR. WALLACE: Objection to form.

17 Let me just point one thing out. You
18 have three different reports here, and you're asking
19 about three different devices; and we have to be very
20 careful about which report we're referring to, if you're
21 asking her specific opinions about the TVTR report
22 because -- and, in fact, if we want to do an hour for
23 each report --

24 MR. DAVIS: Well, see, here's my problem.

1 If we've got to do them all separate, then, frankly, I
2 think I need nine hours, because, you know, I'm entitled
3 to --

4 MR. WALLACE: Well, we have an agreement
5 on this issue. I'm not expecting you to move off your
6 agreement. But let me just point out, I just --
7 all I'm pointing out is I'm assuming we're going
8 to work together and you're going to try to be clear
9 about, if there is a report for you to refer to, you'll
10 ask her to refer to it.

11 MR. DAVIS: Well, okay. I'll try to
12 get -- see if I get a different answer for each report.

13 Q. (BY MR. DAVIS) Let's do them one at a time.

14 For TVTR, does your TVTR report include
15 opinions that TVTR is, in fact, unsafe?

16 A. No. I'm not a physician. What I've done is
17 I've worked with medical device manufacturers, their
18 CEOs. I've worked with design teams and quality
19 representatives. And what I'm opining about is that
20 they didn't follow their own procedures to prevent
21 risks, nor did they follow standards out there that are
22 the fundamental minimum requirements that are -- that
23 enable a manufacturer to prevent risks and, therefore,
24 prevent complaints and how you handle those risks as

1 they come back.

2 Q. Now, if I ask you that same question about
3 TVTO, are you going to have the same answer?

4 A. Could you ask me that question again? I'm
5 sorry. I can't remember -- I was just focusing on --

6 Q. Does your report for TVTO include opinions
7 that TVTO is not safe?

8 A. No. Mine says that for the O, that was -- the
9 risk management was not conducted in a cohesive manner
10 in accordance with their procedures.

11 Q. Okay. And, if you could, because time is
12 important, just answer my question, because I didn't ask
13 you what your report does cover. I asked you -- or
14 other things. I asked you only about whether it
15 covers -- whether it opines that TVTO is not safe.

16 A. Of course.

17 Q. So same question for TVTS. Does your TVTS
18 report include opinions that TVTS is not safe?

19 A. No.

20 MR. WALLACE: Objection to form.

21 Q. (BY MR. DAVIS) Okay. In fact, you would --
22 would you agree you're not qualified to express an
23 opinion on whether any of those three devices are safe?

24 MR. WALLACE: Objection to form.

1 A. I believe I've already stated, and it's in my
2 report, that I am not a medical doctor; and I am not
3 ever going to state something that's a medical opinion.

4 Q. (BY MR. DAVIS) Okay. Now, can you -- is it
5 your opinion that Ethicon did not adequately consider
6 all of the harms associated with TVTR?

7 A. I'm sorry. Did you say "did not ever"? I
8 just --

9 Q. No, "did not adequately consider."

10 A. Is that my opinion? Yes.

11 Q. Okay. Please identify -- just give me a list
12 of the harms that you've opined that Ethicon did not
13 adequately consider relating to TVTR.

14 A. I would need to look at my report, because I
15 don't have it all memorized.

16 MR. DAVIS: Let's go off the record.
17 When you're ready --

18 MR. WALLACE: I don't think we need to go
19 off the record for her just to consult her report.

20 MR. DAVIS: If she's going to take -- use
21 up my time going through her report, you know --

22 MR. WALLACE: Well, that's what you're
23 here to ask her about.

24 MR. DAVIS: Well, I don't think it's fair

1 to require -- let her use up my time.

2 MR. WALLACE: Well, you guys do that at
3 every deposition, though; so the playing field is going
4 to be the same.

5 A. So, for example, it says right here in
6 Table 17 -- or Page 17 that they -- one of the harms
7 they omitted was mesh degradation. They have complaints
8 about mesh fraying and roping, sheathe damage, erosion,
9 exposure, pain -- there are quite a few things that are
10 in my report, specifically Section C, Section VI,
11 specifically calls out risks ignored by Ethicon.

12 Q. (BY MR. DAVIS) But right now, my question is
13 simply to give me a list of the harms that you've opined
14 that Ethicon did not adequately consider.

15 A. Okay. A risk has to do with harm.

16 Q. See, I'm not asking you about -- we're going
17 to get to risk in a minute. I'm asking only about --
18 only about harms right now. I want --

19 A. Degradation, mesh stiffness, roping, curling,
20 deforming, particle loss, difficulty removing.

21 Q. Okay. Can you provide me a definition -- or
22 your definition, rather -- of the term "harm"?

23 A. A hazard is a potential source of harm. Just
24 let me -- let me answer the question. A harm is an

1 injury to a person, an environment, and is quoted from
2 ISO 14971 and EN 1441. So --

3 Q. Okay. Can you give me a complete list --
4 well, no. Strike that.

5 Does your report include opinions that
6 Ethicon did not adequately consider any hazards
7 associated with TVTR?

8 A. Did not adequately?

9 Q. Yes.

10 A. Yes. They did not adequately.

11 Q. Okay. Can you give me just a list of the
12 hazards that you've opined that Ethicon did not
13 adequately consider --

14 MR. WALLACE: Objection to form.

15 Q. (BY MR. DAVIS) -- for TVTR?

16 MR. WALLACE: Objection to form.

17 A. A list of the hazards they did not adequately
18 consider. There were -- to my knowledge, prior to
19 introduction, they did not consider any design hazards.
20 So that would include all of the 11 hazards which are in
21 my report, as well as all of those I previously
22 mentioned, as well as the 11 that are in the report.

23 Q. (BY MR. DAVIS) When you say all those that
24 you previously mentioned, what -- you're referring to

1 your last answer?

2 A. Yes.

3 Q. Okay.

4 A. A hazard is a potential source of harm. You
5 asked about harm. Then you asked about hazards.

6 Q. Yeah. Is it your opinion that "hazard" and
7 "harm" mean the same thing?

8 A. No.

9 Q. Okay.

10 A. But they have a common element.

11 Q. Okay. I just -- for right now, I just want a
12 list of the hazards.

13 A. Okay. I'll find the list -- a list.

14 MR. WALLACE: Objection to form.

15 Q. (BY MR. DAVIS) I want a list of the hazards
16 that you've opined that Ethicon did not adequately
17 assess or consider relating to TVTR.

18 MR. WALLACE: Objection to form.

19 A. Wrong mesh composition, mesh not cuttable,
20 over-tensioning of tape, postoperative erosion,
21 degradation, removal failure. Let me get some more from
22 my list in my report. There is vaginal extrusion,
23 erosion of the urethra, perforation by the mesh,
24 infection of incision, urethral tear, mesh broken, torn

1 mesh, bent needle, mesh kinked, dull needle.

2 Q. Okay. Is that a complete list?

3 MR. WALLACE: Objection to form.

4 Her report's right in front of her. If
5 you're going to make this a memory test --

6 MR. DAVIS: No.

7 MR. WALLACE: -- let's go on the record
8 and just say you want to make this a memory test. This
9 has nothing to do with the report.

10 MR. DAVIS: No, she's got -- she's been
11 going through her report.

12 Q. (BY MR. DAVIS) Have you given me a complete
13 list?

14 MR. WALLACE: Objection to form.

15 That's --

16 A. I've given you a list of what's in the form --
17 in my report.

18 Q. (BY MR. DAVIS) Are there any other hazards
19 that you've opined that Ethicon did not adequately
20 consider relating to TVTR?

21 MR. WALLACE: Objection to form; asked
22 and answered.

23 A. I've presented what's in my report.

24 Q. (BY MR. DAVIS) Okay. How does fraying of

1 mesh harm a person?

2 MR. WALLACE: Objection to form.

3 A. I am not a medical doctor. But what the
4 documentation has showed me, by reviewing the documents
5 in my exhibit list, is that fraying of the mesh can lead
6 to -- when you fray it, it can cause roping; and then it
7 can lead to urinary retention, and particles can cause
8 pain.

9 Q. (BY MR. DAVIS) Okay. And have you
10 reviewed any clinical literature that reports what
11 you've just explained?

12 MR. WALLACE: Objection to form; asked
13 and answered.

14 A. I have reviewed what's on my -- the list.

15 Q. (BY MR. DAVIS) Well, just answer my question.

16 A. And, yes, there was a clinical review in
17 there.

18 Q. Okay. Let me ask you: What is a -- do you
19 know what the acronym "CER" stands for?

20 A. Clinical evaluation report. Is that what
21 you're asking?

22 Q. Okay.

23 A. Yeah.

24 Q. What is a clinical evaluation report?

1 A. It depends on which company you're talking
2 about; but, generally, it's when you look at the
3 literature. And it's a requirement that you look at the
4 literature and you evaluate what's happening with your
5 product and what -- your competitors' products and if
6 there's any new trends that are happening in the -- in
7 the literature regarding your product or like products.

8 Q. Are there any industry standards that relate
9 to clinical evaluation reports?

10 A. You know, I am not someone who does the
11 clinical evaluation reports; but there are known methods
12 used to do those. I couldn't cite which standards there
13 are.

14 Q. Okay.

15 A. I hire people to do those.

16 Q. Would you agree that you're not qualified to
17 pass judgment on the sufficiency of a clinical
18 evaluation report?

19 A. I can tell you if they were performed -- if
20 they were performed, and I can tell you if there are
21 hazards or harms that were not included.

22 Q. Have you reviewed any clinical evaluation
23 reports relating to TVTR?

24 A. If they're on my list, I'm sure that I looked

1 at it; but I don't believe there's anything in my report
2 about clinical evaluation reports.

3 Q. That was going to be my next question. In
4 your TVTR report -- let's take them one at a time -- is
5 there anything in there about clinical evaluation
6 reports?

7 A. You know, off the top of my head, I don't
8 recall. I don't believe so, no.

9 Q. Okay. And did you discuss clinical evaluation
10 reports in either your TVTO report or your TVTS report?

11 A. Without --

12 MR. WALLACE: Objection to form.

13 A. Without reviewing them, my answer is "no."
14 I'm sure that I reviewed things, but I don't believe I
15 called them out and opined about them in my reports.

16 Q. (BY MR. DAVIS) Is a clinical evaluation
17 report an important document to you or not --

18 MR. WALLACE: Objection to form.

19 Q. (BY MR. DAVIS) -- for the work you did in
20 this case?

21 MR. WALLACE: Objection to form.

22 A. No, I'm looking primarily at their design
23 control documents, of which clinical evaluation reports
24 are not traditionally a part; and I'm looking at their

1 risk control documents, and then there could be some
2 clinical -- there should be some people that bring in
3 clinical information as part of that team. But I am not
4 the person that is opining about the evaluation of
5 clinicals. I am not a physician, as I've mentioned
6 several times already.

7 Q. (BY MR. DAVIS) Okay.

8 A. So I am not making medical judgments about the
9 clinical effectiveness.

10 Q. Are clinical evaluation reports part of the
11 risk management process?

12 A. Generally, they -- clinical people -- I just
13 answered that -- clinical people bring in information
14 for that team that does the risk management; but it is
15 not an output of the risk management process.

16 Q. Okay. Are you familiar -- well, let me ask it
17 this way: Who sets the standards for the safety of
18 medical devices in the United States?

19 MR. WALLACE: Objection to form.

20 A. Each company is responsible for defining their
21 thresholds for safety for their products.

22 Q. (BY MR. DAVIS) Okay. But is there
23 a source for who sets the industry standards in
24 the United States that companies are expected to follow,

1 with respect --

2 A. No.

3 Q. -- to the safety of medical devices?

4 Are there --

5 MR. WALLACE: Objection to form.

6 Q. (BY MR. DAVIS) Are there standards in the
7 United States for manufacturers to follow with respect
8 to ensuring the safety of medical devices?

9 A. That's a different question. I must not have
10 understood what you were asking the first time. Are
11 you -- could you -- are you -- what are you asking?
12 Could you repeat that? I must not have understood your
13 question.

14 Q. If you don't understand the question, just say
15 so; and I'll --

16 A. I'm trying to say that now, sir.

17 Q. Sure. That's fine. Let's ask a totally new
18 question.

19 What is the role of the FDA, if any, with
20 respect to establishing safety standards for medical
21 devices in the United States?

22 A. As I understand it, the FDA is out of the
23 scope of this whole project.

24 Q. But that's not my question. Can you just

1 answer my question?

2 MR. WALLACE: Well, ask it again.

3 Q. (BY MR. DAVIS) What role, if any, does the
4 FDA have in connection with setting standards for
5 ensuring the safety of medical devices in the United
6 States?

7 MR. WALLACE: Objection to form.

8 This is well beyond the scope of the
9 report. Are you asking about the P&A process, as
10 well --

11 MR. DAVIS: No.

12 MR. WALLACE: -- or just 510(k)?

13 MR. DAVIS: No, I didn't ask about
14 510(k), not at all.

15 Q. (BY MR. DAVIS) That raises a question.
16 You've talked about design controls, right?

17 A. Yes.

18 Q. You've expressed opinions about Ethicon's
19 compliance with design controls, right?

20 A. Yes, sir.

21 Q. Now, design controls are not part of the
22 510(k) process, are they?

23 A. In order to have an effective 510(k), you need
24 to have design controls.

1 Q. Let me ask it this way: Does 21 CFR Part 820
2 have anything to do with the 510(k) process?

3 MR. WALLACE: Objection to form.

4 A. They are linked, sir.

5 Q. (BY MR. DAVIS) Well, won't you agree with me
6 that 21 CFR Part 820 relates specifically to design
7 controls, among other things?

8 MR. WALLACE: Objection to form.

9 A. You know, the FDA is -- like I've already
10 stated, is outside the scope of this report; but I will
11 say that the 820 regulations and the 13485 regulations
12 are very aligned and cover the same materials. They
13 cover the same design control elements. Additionally,
14 ISO 14971 is a recognized, harmonized standard by the
15 FDA. So they're well aligned. They do not -- they
16 cover the same areas, and they do not contradict each
17 other.

18 (Marked Wilson Exhibit No. 12.)

19 Q. (BY MR. DAVIS) I'll hand you Exhibit 12. Are
20 you familiar with Exhibit 12?

21 A. Of course. That's referenced -- well, let's
22 see what version this is. The 2007 version. Yes, I'm
23 very familiar with that.

24 Q. Of ISO 14971, correct?

1 A. Yes.

2 Q. And with respect to your opinions in your TVTR
3 report, what standards were you opining that Ethicon was
4 not complying with?

5 A. Well, this standard wasn't even applicable to
6 the TVTR; so it would not be this one. If you look in
7 my report, it was ISO 9001; and then there's a medical
8 device supplement, so to speak, that's called EN 46001.
9 Those were both in effect at the time of the TVTR
10 design. And there's an EN 1441 that related to risk
11 management.

12 Q. Well, are you saying your TVTR report doesn't
13 opine that Ethicon failed to comply with any part of
14 Exhibit 12?

15 A. What I'm saying is, at the time of the device
16 design and release, the applicable standards were the
17 ones I just mentioned.

18 Q. Okay. But, see, I'm asking a broader question
19 right now. Have you expressed opinions --

20 A. These weren't out, so how could I express
21 opinions about them?

22 Q. Then why is Exhibit 12 mentioned in your TVTR
23 report?

24 A. Well, because what we were saying is there are

1 standards; and there have been -- continuously have been
2 standards. And it started as early as 1959, back in
3 MIL-STD-9858; and it goes through this date. That was
4 the purpose of it being in that report.

5 Q. Can you -- you've mentioned a MIL-STD. Am I
6 correct?

7 A. Yes.

8 Q. Okay. Can you tell us what that is?

9 A. Yes. It's a quality management system
10 standard that was used in the military and for medical
11 devices and universally way back in 19 -- when I was
12 learning quality 30 years ago.

13 Q. Okay.

14 (Marked Wilson Exhibit No. 13.)

15 Q. (BY MR. DAVIS) Let me hand you Exhibit 13.
16 Is Exhibit 13 the standard you just referred to?

17 A. I believe it is.

18 Q. Okay. And is there any reference to medical
19 company -- or device applications in that standard?

20 MR. WALLACE: Objection to form.

21 A. It is a general standard; and the scope states
22 that it applies to all supplies, equipment, subsystems,
23 and systems or services when referenced by a
24 specification, contract, or order.

1 So, in fact, I actually worked on
2 high-level quadriplegic wheelchairs back around 30 years
3 ago, as well as military components; and we used the
4 same standard back then for quality management systems.
5 So this is not industry-specific, but it's used -- it
6 was used because it's the predecessor of other
7 standards.

8 Q. (BY MR. DAVIS) Okay. Now -- so does
9 Exhibit 12 have any bearing on your TVTR report?

10 A. Let's go back to what that was.

11 Q. ISO 14971:2007, does it have any bearing at
12 all on your TVTR report?

13 A. No.

14 Q. Okay. Can you just tell me why you mentioned
15 it in your report?

16 A. I've already told you that, but I'll be glad
17 to do it again.

18 Q. Okay. If you've given me a complete answer,
19 that's fine.

20 Now let's talk about TVTO. Do you have
21 opinions on TVTO that Ethicon didn't comply with any
22 part of Exhibit 12, ISO 14971:2007 version?

23 A. I'm just thinking of the time frames. For
24 TVTO, I discussed both the 2000 and the 2007 version. I

1 believe I footnote them both. Let me double-check,
2 please. Yes, I do. Both -- I do refer to the 2007
3 version there.

4 Q. But you refer to the 2007 version in your TVTR
5 report, also, right?

6 A. In the section about -- this is a list of
7 standards; and for history's sake, there are lists of
8 standards. But you asked me if I opined about them, I
9 thought.

10 Q. Okay. Let me --

11 A. I'm sorry. I'm trying to answer your question
12 specifically.

13 Q. And I'll try to get more clear.

14 For the TVTO device --

15 A. Yes, sir.

16 Q. -- what sections of Exhibit 12 are you opining
17 that Ethicon failed to comply with?

18 A. Well, for the TVTO, they certainly -- I'm
19 pretty sure they're footnoted, but they certainly -- to
20 just start right off, under 3.2, "Management
21 responsibilities."

22 Q. Okay. What else?

23 A. The section that says that you must
24 continually go back and do this throughout the life

1 cycle of the product. You have to assess and evaluate
2 risks and update your risk management throughout the
3 whole lifetime of your process. Do you want me to find
4 the sections for you?

5 Q. Yeah. Do you know?

6 A. I don't have the sections memorized.

7 Q. Well -- but you --

8 A. But I can look in my report. I just didn't
9 want to take up time. But --

10 Q. I don't think you'll find it in your report,
11 but please look and see if you find it in your report.

12 MR. WALLACE: Objection to form.

13 A. I also -- what was the question? You said I
14 objected to the -- or I opined in the report about the
15 fact that it was not done as a system, and it was done
16 piecemeal. That's in here, too. So if you want to
17 check section by section, it's going to take me a little
18 bit.

19 Q. (BY MR. DAVIS) All I'm asking right now is
20 just to tell me which provisions of Exhibit 12 --

21 A. I'm telling you the provision. I can't call
22 out the section numbers.

23 MR. WALLACE: You're interrupting her
24 now.

1 MR. DAVIS: No, she interrupted me. I
2 was still asking my question. She interrupted me.

3 MR. WALLACE: No.

4 MR. DAVIS: Ed, in all due respect,
5 she -- I was asking a question, and she cut me off.

6 MS. FITZPATRICK: Look, I'm watching
7 this. You've cut her off in every answer. Just let her
8 answer the question, and we'll get out of here quickly.

9 MR. DAVIS: I respectfully disagree.

10 MR. WALLACE: Okay. Go ahead and ask
11 your question. Just --

12 Q. (BY MR. DAVIS) Please simply tell me the
13 sections of Exhibit 12 that you've opined that Ethicon
14 failed to comply with, with respect to TVTO.

15 MR. WALLACE: Objection to form.

16 A. 3.2 --

17 Q. (BY MR. DAVIS) You've already answered that.

18 A. -- 3.3, 3.4, 4.2, 4.3, 4.1 -- sorry, I went
19 out of order there -- 4.4, 6.1, 6.2, 6.3, 6.7, 9. Shall
20 I go through the annexes, as well?

21 Q. I just asked you -- no. Have you finished
22 going through the actual standard?

23 A. There you go.

24 Q. Okay. Now, a minute ago, I believe you said

1 that -- I don't want to put words in your mouth, so you
2 can correct me -- I believe you said something to the
3 effect that one of the problems with TVTO is their FMEA
4 did not examine it on a system level. Or can you
5 explain what you were meaning?

6 MR. WALLACE: Objection to form.

7 A. Could you -- could you clarify your question,
8 please?

9 Q. (BY MR. DAVIS) You used the word "system" a
10 minute ago.

11 A. Right.

12 Q. Can you just tell me what you were referring
13 to?

14 A. Oh. The system is the whole of the device.
15 It's not the parts. So the system would include the
16 instruments on the O. It would be the helical passers,
17 the winged guide. It would include the packaging, the
18 tie-back lid stock. It would include the
19 sterilization -- or, excuse me. I take that back. The
20 system would -- would not include that.

21 But it would be presented as a sterile
22 pack so that -- as part of the system, how it's
23 presented. So it is everything taken together,
24 including the mesh, the method of installation, so in a

1 transobturator approach. All of those together go in to
2 form a system. That's the top level.

3 Q. Okay. And you're saying that Ethicon's FMEA
4 didn't do that?

5 A. No, it did not.

6 Q. Okay. And can you show me in the standard,
7 14971, where there's a requirement to do this system
8 approach that you just described?

9 A. I'd be glad to.

10 Q. Yes, thank you.

11 A. I believe the appropriate -- do you want me to
12 show you in the 2007 one?

13 Q. Well, you tell me whichever standard you're
14 relying on.

15 MR. WALLACE: Objection to form.

16 A. I will be glad to. I'm sure it's footnoted
17 somewhere here. The appropriate one initially, during
18 the design, would be the 2000 version. That's why I --

19 (Marked Wilson Exhibit No. 14.)

20 Q. (BY MR. DAVIS) Please look at Exhibit 14. Is
21 Exhibit 14 the version you just referred to?

22 MR. WALLACE: Objection to form.

23 You mean the 2000 version?

24 A. This does say --

1 Q. (BY MR. DAVIS) Is Exhibit 14 the 2000 version
2 of ISO 14971 that you just referred to?

3 A. It's -- no, it's not. It's an ANSI/AAMI/ISO
4 version, but the actual -- it's fine to use. I'd be
5 glad to use it.

6 Q. Well, other than the title page, aren't the
7 standards the same?

8 A. I just want to be clear for the record that
9 it's not what you called out.

10 Q. But now answer my question.

11 A. I'm working on it.

12 Q. No. I've got --

13 MR. WALLACE: Paul, you just --

14 A. You want the --

15 Q. (BY MR. DAVIS) No, I haven't gotten to that
16 one yet. I haven't asked that question yet for this
17 2000 version.

18 A. Could you repeat your question, please?

19 Q. Yes, ma'am.

20 Is the substance of the contents of
21 Exhibit 14, the 2000 version of ISO 14971, on which you
22 relied for your TVTO report?

23 MR. WALLACE: Objection to form.

24 A. Yes.

1 Q. (BY MR. DAVIS) Thank you. Now I'll ask the
2 question. Please identify --

3 A. It is one of them.

4 Q. Okay. Now please identify the provision of
5 Exhibit 14 where it requires this system approach to the
6 FMEA.

7 A. This is very hard to read, it's so light.
8 So -- so what they call -- it is a device. A device is
9 the entirety of a device. It is not a component. That
10 is right in Section 3.1 at the very -- and 3.2. They
11 shall establish and maintain a process for identifying
12 hazards associated with a medical device.

13 Q. Okay. And did they somehow, in your opinion,
14 suddenly change that standard in moving to the 2007
15 version of ISO 14971?

16 A. No. They both --

17 MR. WALLACE: Objection to form.

18 A. -- apply to a device.

19 Q. (BY MR. DAVIS) Okay. And -- so let's go back
20 to Exhibit 12 for just a minute. Can you turn to
21 Page 9?

22 A. (Complying).

23 Q. You see Section -- right above Section 4.2 is
24 the carryover part of Section 4.1 that you, a few

1 minutes ago, said that Ethicon did not comply with, with
2 respect to TVTO. Do you recall that?

3 MR. WALLACE: Objection to form.

4 A. I was looking where you said.

5 Q. (BY MR. DAVIS) Do you recall that a few
6 minutes ago, you opined that Section 4.1 of Exhibit 12
7 is one of the sections that Ethicon failed to comply
8 with, with respect to TVTO?

9 MR. WALLACE: Objection to form; asked
10 and answered.

11 Her testimony is what it is.

12 A. If that's what I said, then that's what I
13 said. I believe so.

14 Q. (BY MR. DAVIS) Okay. Let's look at Note 5.
15 Do you see where Note 5 says: "The scope of the risk
16 analysis can be very broad," parenthesis, "as for the
17 development of a new device with which a manufacturer
18 has little or no experience," close parenthesis, "or the
19 scope can be limited," parenthesis, "as for analyzing
20 the impact of a change to an existing device for which
21 much information already exists in the manufacturer's
22 files," close parenthesis, unquote.

23 Did I read that correctly?

24 A. You read Note 5 correctly.

1 Q. And do you apply Note 5 in your practice?

2 A. In fact, this is a very important
3 consideration, yes.

4 Q. So you agree that a -- that if you make a
5 change to a device, you can have a very limited FEMA,
6 right?

7 MR. WALLACE: Objection to form.

8 A. No, I do not agree with that. If you make a
9 change to the -- a device that's a whole new surgical
10 approach -- new instruments, new attachment method, new
11 way of installing it -- that is a whole new device that
12 says, right here, the scope can be broad as for the
13 development of a new device which has little or no
14 experience.

15 For the TVTO, there was no -- little or no
16 experience; and the device was not the same. So it
17 tells me exactly as I applied it to my report.

18 Q. (BY MR. DAVIS) What parts of the TVTO system
19 were not included in the risk analysis?

20 A. Well, one would be the mesh and how it's
21 attached. They started just doing it with a -- it's
22 right here in the report. As you can see in the
23 table -- I believe it's Table 1 -- they didn't even do a
24 design FMEA on the design of the device. So --

1 Q. My last question was simply: First, tell me
2 what components of the system --

3 A. The mesh.

4 Q. -- did they not -- any others?

5 A. The attachment mechanism to the mesh.

6 Q. What do you mean by that?

7 A. Let's just look at my -- let's look at the
8 differences. So they didn't consider the mesh at all.

9 Q. You've told me about the mesh three times.
10 Are there any others?

11 A. Just give me a moment, please, sir. So what
12 they didn't do is look at how the system works together.
13 So -- please let me finish -- you can't say -- one, you
14 can't say that the components equal to the sum of the
15 parts. That's the false logic. You cannot say because
16 you looked at a little dib (sic) over here and a little
17 dabble over here, that when you put them together, it
18 will work. And that is what I've been trying to state.
19 They did not look at those changes that were different.

20 MR. WALLACE: Do you want me to help you
21 cut to the chase?

22 THE WITNESS: Yeah, because --

23 MR. DAVIS: Sure.

24 MR. WALLACE: (Indicating).

1 THE WITNESS: Right there, yeah. Thank
2 you. I knew it was in here somewhere.

3 A. So they didn't look at the technique, the
4 surgical technique, and how it was fixated. They didn't
5 look at how it was implanted. I mentioned those,
6 through the obturator membrane. They didn't look how
7 the change to the mesh ends and how that would work with
8 the helical passers and the winged guide and how that
9 would work, to the needles connected on the delivery
10 system. So --

11 Q. (BY MR. DAVIS) Okay. Will you agree that the
12 2007 version of ISO 14971 includes a discussion of some
13 examples of risk analysis techniques?

14 A. In the annex?

15 Q. Yes.

16 A. Yes.

17 Q. And could you turn to that? Do you see
18 Annex G?

19 MR. WALLACE: And after this, we're going
20 to take a break.

21 MR. DAVIS: Sure.

22 Q. (BY MR. DAVIS) Do you see -- well, first of
23 all, is there any provision anywhere in ISO 14971 that
24 requires the use of an FMEA to do a risk analysis? Is

1 that anywhere in the ISO?

2 A. No.

3 Q. Okay. Is it in any standard that applies to
4 Ethicon? Any industry standard, I'm talking about. Is
5 there any industry standard that requires the FMEA
6 approach to risk analysis?

7 MR. WALLACE: Objection to form.

8 A. That tool is not a requirement.

9 Q. (BY MR. DAVIS) Okay. Now -- and do you see
10 where, in Annex G of Exhibit 12, they do give a general
11 description of what an FMEA is, correct?

12 A. Yes. And Ethicon has chosen the FMEA to be
13 their tool to do risk analysis. It's in their
14 procedures.

15 Q. They chose that at certain times, correct?

16 A. They've chosen that -- it was throughout the
17 life of these products.

18 Q. Okay. Throughout the life of TVTR?

19 A. In each of these cases, it talks about the
20 procedures.

21 Q. Okay.

22 A. And that was the only tool of these that were
23 used.

24 Q. Okay. And would you agree that an FMEA is a

1 technique by which you look at the effect of individual
2 components systematically?

3 A. You look at -- no.

4 Q. Okay. How would you describe an FMEA? What
5 is -- describe that technique.

6 A. You look at the failures associated with any
7 failure modes that can happen with a device. It could
8 be with a component, but it doesn't have to be. It's a
9 systematic --

10 Q. I'm going to stop at one more question.

11 A. It's a systemic approach to look at how a
12 device can fail --

13 Q. Okay.

14 A. -- and rank that failure in severity and
15 probability of occurrence.

16 Q. Would you agree that in an FMEA, that
17 technique involves taking one component at a time and
18 evaluating it?

19 A. No, you do not need to do it that way.

20 MR. DAVIS: Okay. We can take a break.

21 (Break from 10:58 a.m. to 11:07 a.m.)

22 Q. (BY MR. DAVIS) I can't remember if I asked
23 this specific question already, so I want to make sure
24 I've got it.

1 Back to clinical evaluation reports. I
2 can't remember. Are they a part of the risk management
3 process?

4 MR. WALLACE: Objection to form.

5 A. I believe I already stated for the record that
6 they are not an output of the risk management process.

7 Q. (BY MR. DAVIS) Okay. Now, if you would,
8 please turn to -- back to Exhibit 12, ISO 14971:2007.
9 Could you turn to Page 22 for a moment, please, ma'am?

10 A. Uh-huh.

11 Q. Do you see Section A.2.9?

12 A. I see it.

13 Q. And then about halfway down in that paragraph,
14 that first paragraph in that section, there's a sentence
15 that starts with the word "however." Can you find that
16 sentence?

17 A. Yes, sir.

18 Q. Do you see where it says, quote: "However, no
19 amount of modeling can substitute for an actual medical
20 device in the hands of actual users. Therefore, the
21 manufacturer should monitor production and
22 post-production information for data and information
23 that can affect their risk estimates and, consequently,
24 their risk management decisions. The manufacturer

1 should also take into account state-of-the-art
2 considerations and the practicability of applying them,"
3 unquote.

4 Did I read that part correctly?

5 A. Yes, you did.

6 Q. Do you agree with that principle that I've
7 just read?

8 A. Absolutely.

9 Q. Okay. And are you -- do you know what the
10 state of the art is -- strike that.

11 Back at the time TVTO was developed, do
12 you know what the state of the art was for SUI
13 treatment?

14 MR. WALLACE: Objection to form.

15 A. That question has no bearing on that
16 Section 829. What this is saying is that the
17 post-production information has to be incorporated into
18 your risk management process; and, yes, I do agree with
19 that statement.

20 Q. (BY MR. DAVIS) Okay. And what does "state of
21 the art" mean, as stated in this paragraph?

22 A. The state of the art, I believe, is defined
23 here. It is like current -- in accordance with current
24 technology.

1 Q. Okay. If you turn to Page 39, do you see they
2 actually define "state of the art"?

3 A. I knew it was in here somewhere. I didn't
4 know what page. Let's see. Where is it here?

5 Q. I don't think you're on the correct page.
6 Page 39.

7 A. 39.

8 Q. You see at the bottom of Page 39, they
9 actually define, quote, "State of the art," unquote, "is
10 used here to mean what is currently and generally
11 accepted as good practice," unquote.

12 A. Okay.

13 Q. Do you accept that definition?

14 A. Of course.

15 Q. Okay. And have you gone back, as part of your
16 work in this case, and tried to understand what was the
17 state of the art back at the time of the development of
18 TVTO?

19 A. With respect to risk management practices,
20 yes.

21 Q. Okay. In any other respect?

22 A. In respect to design control, yes.

23 Q. Okay. Any other aspects of state of the art
24 that you tried to understand what it was at that time?

1 MR. WALLACE: Objection to form.

2 A. Those are the topics that I've been asked to
3 talk about, so that's what I reviewed.

4 Q. (BY MR. DAVIS) Okay. Do you have any
5 experience in making benefit/risk determinations?

6 A. Personally, I do not.

7 Q. Okay.

8 A. We usually get the clinicians to do that part
9 after the risk management is done, and that's what's --
10 it's in accordance with the standards.

11 Q. Okay. Do you have any education, training, or
12 experience that would allow you to evaluate someone
13 else's benefit/risk analysis?

14 MR. WALLACE: Objection to form.

15 A. You know, I do. I've worked in quality
16 regulatory risk management. I've worked in over a dozen
17 different kinds of implantable medical devices. So I do
18 know what's generally accepted and what was done in
19 2003. I lived it. I've looked at a lot of different
20 medical device, implantable device companies. And so I
21 think I'm fairly well acquainted with what's appropriate
22 for our risk/benefit decision back in that time frame,
23 and how it's changed over time.

24 (Marked Wilson Exhibit No. 15.)

1 Q. (BY MR. DAVIS) Let me hand you Exhibit 15.

2 Are you familiar with this guidance issued by the FDA?

3 A. You know what? I am not. This is a 2012

4 standard. So I believe I've seen it. I have not -- it

5 depends when you say "familiar." I've seen it, but I

6 haven't memorized it.

7 Q. Okay.

8 A. And it certainly wasn't applicable at the time

9 of the TVTO.

10 Q. Well, for just a moment on Exhibit 15, if you

11 would, turn to Page 14.

12 MR. WALLACE: Do me a favor. Oh, you

13 gave me --

14 MR. DAVIS: Yeah.

15 Q. (BY MR. DAVIS) Do you see on Page 14 of that

16 exhibit, they begin a list of several pages of examples

17 for -- examples of benefit/risk determinations?

18 MR. WALLACE: You know this is a 55-page

19 document. Do you want her to read the whole thing?

20 MR. DAVIS: No.

21 A. And it's an FDA document which is out of the

22 scope.

23 Q. (BY MR. DAVIS) I asked you a very simple

24 question.

1 A. Okay. I'm not on Page 14. Hold on. Go
2 ahead.

3 Q. Do you see at the beginning on Page 14, it
4 simply lists several examples of benefit/risk
5 determinations?

6 MR. WALLACE: Are you referring to the
7 one example?

8 A. There is --

9 Q. (BY MR. DAVIS) I said over the next several
10 pages, there's examples to --

11 A. I thought you said on Page 14.

12 Q. I said it begins.

13 MR. WALLACE: No, you didn't.

14 MR. DAVIS: Well, the record is what it
15 is.

16 A. Okay.

17 Q. (BY MR. DAVIS) I'm not -- I have no plans to
18 go into detailed questions about these. I'm just asking
19 right now: Do you see that they list some examples?

20 A. There is an example on Page 14, an example
21 on 16. Looks like a third example is on 17. So I do
22 see three examples over the next few pages.

23 Q. Well --

24 A. Oh, there's some more, an example on Page 19.

1 Q. Okay. So my follow-up question is: In your
2 practice, do you ever have occasion to need to look at
3 FDA guidance documents?

4 A. We look at them all the time.

5 Q. Okay. And do you rely upon FDA guidelines
6 documents?

7 MR. WALLACE: For what?

8 Objection to form.

9 Q. (BY MR. DAVIS) For any purpose.

10 A. How does that relate to my reports here?

11 Q. You don't need to worry about that,
12 Ms. Wilson. Just --

13 A. I believe --

14 MR. WALLACE: I wouldn't take advice from
15 Mr. Davis. But go ahead and answer the question, if
16 there's a question pending.

17 A. I look at FDA guidance documents all the time.

18 Q. (BY MR. DAVIS) Okay. And do you have
19 occasion to rely on them?

20 MR. WALLACE: Objection to form; asked
21 and answered.

22 A. They're guidance, and we use them as guidance.

23 Q. (BY MR. DAVIS) Okay. Have you worked on a
24 team that used FDA guidance documents in connection with

1 benefit/risk analyses?

2 MR. WALLACE: Objection to form.

3 A. What I already stated was we generally rely on
4 the clinician to perform them, but we would use the
5 guidance documents. And I have not personally done that
6 because I have a regulatory person on my team. And
7 that's not within the scope of what I've been asked to
8 do.

9 Q. (BY MR. DAVIS) Okay. Do you have any
10 expertise in the technology relating to the TVT, TVTR,
11 and TVTO and TVTS?

12 MR. WALLACE: Objection to form.

13 A. Could you clarify what you mean by
14 "technology," please?

15 Q. (BY MR. DAVIS) Well, the underlying
16 technology behind TVT products, do you have any
17 expertise in it?

18 A. I don't know. If you're talking about -- for
19 example, I do have knowledge of medical material
20 molding. Or are you talking about knitting or cutting?
21 So if you could be -- or all of the above, if that's --

22 Q. Okay. Do you have any expertise in the
23 application of TVT devices?

24 MR. WALLACE: Objection to form.

1 A. No.

2 Q. (BY MR. DAVIS) Do you have --

3 A. I've never installed one.

4 Q. Do you have any expertise in the research
5 methodology for performing a clinical evaluation?

6 MR. WALLACE: Objection to form.

7 A. I thought we already covered clinical
8 evaluations, and that I am not a physician. I am not a
9 design engineer. So I am not going to be able to talk
10 about either of those categories, and it is so footnoted
11 in my reports.

12 Q. (BY MR. DAVIS) Do you have any expertise in
13 the diagnosis or management of stress urinary
14 incontinence?

15 A. That is what a physician does.

16 Q. Okay. Would you agree that it's beyond the
17 scope of your three reports for you to attempt to opine
18 that any of the risks associated with TVTR, TVTO, or
19 TVTS are unacceptable?

20 MR. WALLACE: Objection to form.

21 A. I can tell you very -- with much confidence
22 whether the risk management process or the design
23 control process have been performed correctly; and, yes,
24 I feel very comfortable.

1 Q. (BY MR. DAVIS) But that's not my question.

2 MR. DAVIS: Just read back my question,
3 please.

4 (The requested portion was read.)

5 MR. WALLACE: Objection to form.

6 A. No. I believe it is stated in my report that
7 these risks are unacceptable because they are in the
8 field, causing harm.

9 Q. (BY MR. DAVIS) Okay. But you're not
10 qualified -- or strike that.

11 What is the purpose of a benefit/risk
12 analysis?

13 A. What you do -- it depends what time frame.
14 Are you talking about 2000 or 2007 --

15 Q. Let's talk about 2000.

16 A. -- or 2012?

17 Q. 2000. Let's start there.

18 A. So you do your risk management process using
19 whatever tool is selected, and it's up to each company
20 to select a tool -- Ethicon chose FMEA -- and they have
21 to choose the threshold. And based on that threshold,
22 if there's something that exceeds those thresholds, you
23 have to say, "Okay. Now does the benefit outweigh the
24 risk?"

1 Q. But that's not -- my question was simply --

2 A. That was your question, sir.

3 Q. No. My question was: What is the purpose of
4 a benefit/risk analysis?

5 A. That was the purpose, to see if you've matched
6 your -- once you've exceeded your self-defined
7 threshold, to see if the benefit of that device
8 exceeds -- excuse me -- if the benefit exceeds the
9 risks. That is exactly what the purpose is.

10 Q. What was the purpose of a benefit/risk
11 analysis in 2007?

12 MR. WALLACE: Objection to form.

13 A. It is the same. It changes in 2012, where you
14 have to do it differently.

15 Q. (BY MR. DAVIS) Okay. What was the purpose of
16 benefit/risk assessment as of 2012?

17 A. Then you have to -- in 2012, they changed it.
18 So you can't look at it holistically. You have to look
19 at it by failure, by failure. So you can't say, "Is the
20 overall benefit for this device still outweighed?" You
21 have to say, "Oh, is the benefit for this" -- say,
22 degradation -- "is that still outweighed?" You have to
23 say, "Boy, we can't get the implant out. So is that
24 still" -- so you have to look step by step in 2012.

1 Q. And what document are you referring to now?

2 A. The 2012 14971 standard.

3 Q. And that has not been recognized as a
4 consistent standard in the United States, has it?

5 A. It certainly is used throughout the world. It
6 has not been recognized in -- in the United States.

7 Q. Okay.

8 (Marked Wilson Exhibit No. 16.)

9 Q. (BY MR. DAVIS) Let me hand you Exhibit 16.
10 Have you ever seen Exhibit 16?

11 A. 2013? You know, I don't recall, honestly,
12 because I don't think any of my reports even go to 2013,
13 except where there was a footnote. But nothing in --
14 nothing in O would go out that far. I could spend some
15 time -- let's see if it's footnoted.

16 Q. Ma'am, I'll represent to you it's not
17 footnoted in your report.

18 A. Yeah. And, you know, I don't -- I don't
19 recall. If you want me to go through it --

20 Q. No, I'm not -- I'm just asking you: Do you
21 ever remember seeing --

22 A. I don't recall.

23 Q. Okay. And if you would, turn to Page 283 of
24 335 of that exhibit.

1 MR. WALLACE: So she's saying that -- she
2 said that she doesn't recall seeing it, yet you're still
3 going to ask her questions about this 335-page document?

4 MR. DAVIS: You haven't even heard the
5 question yet, Ed. Just please be patient.

6 MR. WALLACE: I'll give you one.

7 Q. (BY MR. DAVIS) On this page, you see there's
8 a reference -- a list of reference documents. You see
9 the reference guidelines on "Medical Devices -
10 Evaluation of Clinical Data"?

11 A. Uh-huh.

12 Q. And it refers to MedDev 2.7.1.

13 A. Yeah. There's a whole bunch of MedDev
14 standards out there.

15 Q. What are the MedDev standards?

16 A. They're guidance documents in Europe.

17 Q. Okay. Are you familiar with this particular
18 one?

19 A. No. I think I've stated on numerous
20 occasions, I don't evaluate clinical data personally;
21 nor was it the scope of this report.

22 Q. Okay. I believe you did cite a MedDev
23 guidance document in your report.

24 A. I did. I did. And that was about post-market

1 surveillance. You're absolutely correct.

2 Q. Okay.

3 (Marked Wilson Exhibit No. 17.)

4 Q. (BY MR. DAVIS) Given your last answers, I
5 won't spend much time on this; but can you see that
6 Exhibit 17 is the MedDev document that's referred to as
7 the first entry on Page 283 of Exhibit 16?

8 A. 283, you said?

9 Q. Yes, ma'am.

10 A. The titles are not exactly the same, but it
11 looks to be the same standard due to the number.

12 Q. I mean, you can see it's the MedDev 2.7.1.

13 A. Right. That's what I just stated.

14 Q. Okay. And you see the -- on that same page,
15 283, do you see the next entry is referencing a GHTF
16 document? Do you know what the "GHTF" stands for?

17 A. Yes, Global Harmonized (sic) Task Force.

18 (Marked Wilson Exhibit No. 18.)

19 Q. (BY MR. DAVIS) Can you tell us, does
20 Exhibit 18 appear to be the Global Harmonization Task
21 Force document that is the second entry on that page of
22 Exhibit 16?

23 A. It does.

24 Q. And are you familiar with that exhibit, 18?

1 A. As I've stated before, I don't personally do
2 clinical evaluations; so I am not familiar with this
3 exact guidance.

4 Q. Okay. Are you -- do you have any experience
5 in the use of ISO 14155?

6 A. What's that number? What's the title that
7 goes with that?

8 Q. Let me just hand it to you.

9 A. That would be handy.

10 (Marked Wilson Exhibit No. 19.)

11 Q. (BY MR. DAVIS) I'll hand you Exhibit 19.

12 A. You know, I believe I've seen this one before;
13 but it hasn't been recently.

14 Q. Okay. Well, I'll represent to you that
15 Annex A to Exhibit 19 -- if you'll turn to Page 15 of
16 the document, I'll represent to you that it is a
17 reference material in ISO 14971. Do you recall that?

18 MR. WALLACE: Objection to form.

19 A. There are many references. No, I don't recall
20 it.

21 Q. (BY MR. DAVIS) Okay. If you would, turn back
22 to Exhibit 12 again.

23 A. Let's see here. 12, that should be the 14971
24 document, 2007, right?

1 MR. WALLACE: You got it?

2 THE WITNESS: No, this is 2000,

3 Exhibit 14. Is that under here?

4 Q. (BY MR. DAVIS) I tell you what. We can
5 just --

6 A. I've got it. It's right here, I think. 12.

7 All right. I've found 12.

8 Q. If you look at Page 80 --

9 A. Okay. Yes.

10 Q. -- do you see Entry No. 10 on Page 80? They
11 list ISO 14155.

12 A. Yes. That's one of 42 references in the
13 standard.

14 Q. And I simply want to make sure that I
15 understand correctly. Now, do you have any experience
16 in the use and application of this ISO, Exhibit 19?

17 A. Let me try to be very clear. As part of a
18 risk/benefit decision, you will get clinicians to help
19 you with that. The clinicians would -- and regulatory
20 folks would refer to something like this, but I don't
21 personally use that standard.

22 Q. Okay.

23 (Marked Wilson Exhibit No. 20.)

24 Q. (BY MR. DAVIS) Let me hand you Exhibit 20.

1 A. Uh-huh.

2 Q. Are you familiar with that clinical evaluation
3 report?

4 A. 2010, the TVT -- you know, I really just don't
5 recall.

6 Q. Okay.

7 A. Because --

8 (Marked Wilson Exhibit No. 21.)

9 Q. (BY MR. DAVIS) Let me hand you Exhibit 21.
10 Are you familiar with that clinical --

11 MR. WALLACE: Are you done with 20?

12 MR. DAVIS: Yes, sir. I gave you a copy,
13 if you want it.

14 A. What's the date of this? 2000? I do remember
15 reviewing this one.

16 Q. (BY MR. DAVIS) Okay. You can see where the
17 doctor is performing a risk/benefit analysis, right --

18 A. Yes.

19 Q. -- in Exhibit 21? Okay.

20 (Marked Wilson Exhibit No. 22.)

21 Q. (BY MR. DAVIS) Let me hand you Exhibit 22.
22 Are you familiar with this clinical expert report?

23 MR. WALLACE: Objection to form.

24 A. Yes, I recall this one.

1 Q. (BY MR. DAVIS) Okay. And, again, since
2 you're not a medical doctor, would it be fair to say you
3 have not tried to opine on this report?

4 A. I have not opined on that specific report.

5 Q. In your work in this case, did you make any
6 inquiries to see if there were any risk analyses for the
7 Prolene mesh that Ethicon manufactures?

8 MR. WALLACE: Objection to form.

9 A. Yes.

10 Q. (BY MR. DAVIS) Okay. Did you -- did you look
11 at any risk analysis of the -- of just the Prolene mesh?

12 MR. WALLACE: Objection to form.

13 A. There was a PFMEA done by Ethicon on the mesh.

14 Q. (BY MR. DAVIS) Okay. That's a Process FMEA?

15 A. Yes, sir.

16 Q. Did you -- and why did you want to look at
17 that?

18 A. Because it has to do with the overall risk
19 analysis.

20 Q. Okay. Did you ask for any design FMEAs
21 relating to just the Prolene mesh?

22 A. I asked for any and all documents related to
23 risk, whether it was design, application, process,
24 summary reports, anything -- anything to do like that.

1 Q. Okay. And you know that Ethicon has used
2 different formats, sometimes FMEA and sometimes other
3 formats for this analysis?

4 A. Well, they have DDSA. The only tool that was
5 used to systematically analyze risk, that I saw used,
6 was an FMEA.

7 Q. Okay. But is it fair to say that you asked
8 for all --

9 A. Any and all.

10 Q. -- risk analysis documents that relate to the
11 Prolene mesh in general?

12 A. I think I just answered that three times, sir.

13 Q. The answer is "yes"?

14 A. Yes.

15 Q. Okay. And why was that important to you?

16 A. Because that's part of each of the systems or
17 devices.

18 Q. Okay. And did you -- were you provided any
19 risk analysis documents dated prior to 1999?

20 MR. WALLACE: Objection to form.

21 A. What product are we talking about now?

22 Q. (BY MR. DAVIS) Prolene mesh in general.

23 A. The --

24 MR. WALLACE: Objection to form.

1 A. -- only document prior to 1999 was the AFMEA
2 done by MedScan, which was also called the Preventia.

3 Q. (BY MR. DAVIS) Okay.

4 A. Oh, wait. 1999. Let's see. That's when they
5 moved it over.

6 (Marked Wilson Exhibit No. 23.)

7 Q. (BY MR. DAVIS) Okay. Let me hand you
8 Exhibit 23. Would you agree that you have not reviewed
9 this risk analysis document before today?

10 A. Let me take a look. Okay?

11 MR. WALLACE: Objection to form.

12 Q. (BY MR. DAVIS) Sure.

13 MR. WALLACE: And it assumes facts not in
14 evidence. So you have -- well, go ahead.

15 Object to form.

16 A. This is -- when I said I looked at it, I meant
17 for TVT product, mesh related to TVT.

18 Q. (BY MR. DAVIS) My questions for the last five
19 minutes -- I asked you very clearly about just Prolene
20 mesh in general.

21 A. Well --

22 MR. WALLACE: No, you weren't clear about
23 it.

24 A. I am sorry. I have never said anything about

1 anything other than TVT, nor are my reports anything
2 other than TVT.

3 Q. (BY MR. DAVIS) Okay. So let me --

4 A. So it was my assumption that you were talking
5 about TVT mesh.

6 Q. Fair enough. So let me just follow up, then.

7 A. Okay. Please do.

8 Q. Would it be important to you to try to see any
9 and all risk analyses that relate to the mesh in
10 general?

11 A. No. It would be important to me that -- if
12 they relate to the intended use, because that's directly
13 what this environment is going to be.

14 Q. Okay.

15 A. So something like a suture or a hernia mesh,
16 that's apples and oranges to me.

17 Q. What if it was for -- in part, to be used
18 for -- to help repair fascial defects in the pelvic
19 area?

20 A. If it's going to be used in the woman's
21 vagina, that would be very useful.

22 Q. Okay. So have you ever seen that Exhibit 23
23 before today?

24 A. I don't believe so, no.

1 Q. Okay.

2 (Marked Wilson Exhibit No. 24.)

3 Q. (BY MR. DAVIS) And have you ever seen
4 Exhibit 24 before today? And I'm going to hand that one
5 to you. It's the next document I'm handing you.

6 A. Right. I'm still looking at the first one.

7 THE WITNESS: Is that the second one?

8 MR. WALLACE: Yeah.

9 THE WITNESS: Let's see. 1997. Is this
10 different than this one? They are different.

11 MR. WALLACE: Is there a question
12 pending?

13 MR. DAVIS: Yeah, I just asked her had
14 she ever seen this risk analysis before today,
15 Exhibit 24.

16 MR. WALLACE: Are you saying it's a risk
17 analysis? Are you representing that to her?

18 MR. DAVIS: I'm not representing
19 anything.

20 Q. (BY MR. DAVIS) But you can read the title of
21 the document.

22 A. I don't believe I've seen this, but I'll be
23 glad to take a look if it has to do with TVT products.

24 Q. Do you see where it relates to the mesh, the

1 Prolene mesh?

2 A. I didn't say that. I asked if it had anything
3 to do with my reports.

4 Q. So it's your belief that this risk analysis,
5 if it relates just to the Prolene mesh, is totally
6 irrelevant. Is that your opinion?

7 MR. WALLACE: Objection to form on that.
8 You're misstating her testimony. She asked you a
9 question that you're unwilling to answer.

10 A. I asked if it had to do with any of the TVT
11 products.

12 Q. (BY MR. DAVIS) And I'm asking you: Do you --
13 is this -- if this report --

14 A. I have not seen this before, no, sir.

15 Q. No, let me just -- let me finish my question,
16 please, ma'am.

17 A. That was your question before this.

18 Q. No, ma'am. Will you allow me to ask it?

19 Exhibit 24 --

20 A. Uh-huh.

21 Q. -- if that exhibit relates solely to Prolene
22 mesh, not to TVT in particular, is it your opinion that
23 this report is not relevant to you?

24 MR. WALLACE: Objection to form.

1 A. No, that's not what I said.

2 Q. (BY MR. DAVIS) Okay. So you would want to
3 see this document if it -- and analyze it if it relates
4 to Prolene mesh in general?

5 A. No, that is not --

6 MR. WALLACE: Objection to form.

7 A. -- what I said, either.

8 Q. (BY MR. DAVIS) Okay. Tell me what you said.

9 A. What I said is: Is it in the same intended
10 use environment? Is it used in the woman's vagina in
11 the same manner? That's how you go about starting your
12 risk analysis.

13 Q. Okay. As part of your work in this case --
14 well, are you familiar with the concept of a
15 biocompatibility risk assessment?

16 A. Yes, sir.

17 Q. Okay. What is that?

18 A. Well, you generally look at the materials of
19 construction and -- after processing and see if they're
20 in compliance with 10993 --

21 Q. Okay.

22 A. -- which is an ISO standard.

23 Q. And does ISO 10993 have anything to do with
24 degradation?

1 A. You know, I hire a microbiologist to handle
2 the ISO 10993 analyses, in particular; so I would have
3 to go and study that. It has to -- I do know it has to
4 do with genotoxicity and if there's any cytotoxicity and
5 things like that, but I couldn't answer that question.

6 Q. When you need some work done under ISO 10993,
7 it sounds like I hear you saying you usually contract
8 that out to third parties?

9 MR. WALLACE: Objection to form.

10 "Work" meaning?

11 A. I have consultants that work for me that are
12 qualified microbiologists that have worked in ISO 10993
13 for many years.

14 Q. (BY MR. DAVIS) Okay. Let me ask a different
15 question, then.

16 Do you have any personal experience,
17 expertise, in working with ISO 10993?

18 MR. WALLACE: "Working with," what do you
19 mean?

20 Q. (BY MR. DAVIS) Well, let me ask it this way:
21 Do you have -- or do you consider yourself an expert on
22 the application of ISO 10993?

23 A. No, I don't.

24 Q. Okay.

1 MR. WALLACE: In what context? You mean
2 performing experiments?

3 Q. (BY MR. DAVIS) In any context at all.

4 A. An expert?

5 Q. Yes.

6 MR. WALLACE: I'm going to object to
7 form. You're -- you're confusing the issues.

8 A. I would not say I'm an expert. I have looked
9 at a lot of documents related to biocompatibility, but I
10 am not an expert.

11 Q. Do you have the expertise necessary to
12 evaluate a biocompatibility risk assessment under
13 ISO 10993?

14 MR. WALLACE: Objection to form.

15 A. I could evaluate that, yes.

16 Q. (BY MR. DAVIS) Okay. How would you go about
17 it?

18 A. I would compare the risk assessment to the
19 standard and perform a gap analysis, and that's how I
20 would go about doing it.

21 Q. You said you would compare it to the standard.
22 You would compare it to ISO 10993?

23 A. Yes. And if I needed experts that are more
24 than me after I evaluated it, I would call them in.

1 Q. Okay. Have you reviewed any biocompatibility
2 assessments relating to Prolene mesh in connection with
3 your work in this case?

4 A. Could you clarify if you mean with respect to
5 the TVT products, please?

6 Q. Okay. I'll break it down. I'll ask you that
7 question first.

8 Have you reviewed any biocompatibility
9 risk assessments relating to a TVT -- to the mesh used
10 in TVT?

11 A. Yes, I have.

12 Q. Okay. Did you attempt to evaluate it under
13 ISO 10993?

14 A. You know, I did look to see if it was
15 reasonable and take a look at it, and if it was
16 complete; but I did not go back to 10993 step by step by
17 step because that wasn't -- I did not do that.

18 Q. Because I didn't see biocompatibility risk
19 assessments discussed in any of your three reports. Did
20 I overlook something?

21 A. I did not opine about it, but I did review
22 one. I thought that was your question.

23 Q. Okay.

24 THE WITNESS: I'm going to get another

1 water.

2 MR. DAVIS: Yeah, let's take a break for
3 a second.

4 (Break from 11:47 a.m. to 12:01 p.m.)

5 Q. (BY MR. DAVIS) Ms. Wilson, way back early on
6 in the deposition today, I had asked you to list for me
7 all the hazards associated with each of the three
8 devices at issue; and you gave me a list. But my
9 recollection is you were looking at a document, and I
10 failed to ask you: What were you looking at when you
11 gave me your list of hazards that Ethicon did not
12 adequately consider?

13 A. I think we were talking about the TVTR, right?

14 Q. Okay.

15 A. And we haven't touched on "S," so it can't be
16 that. And there were -- in my report, there were
17 hazards listed.

18 Q. Okay. I just wanted to make sure I understood
19 what you were reading from. You were looking at your
20 report?

21 A. Yes.

22 Q. That's fine. That's all I wanted to clarify.
23 Now I want to follow up for TVT0.

24 A. Uh-huh.

1 Q. Can you give me a list of the hazards that
2 you've opined that Ethicon failed to adequately assess?

3 A. I'll be glad to. That would be all of these
4 listed on Page -- Table 2.

5 Q. Of your report?

6 A. Do you want me to call them out individually?

7 Q. No. What page of your report is Table 2?

8 A. 17.

9 Q. That's fine.

10 A. And 18.

11 Q. Okay.

12 A. There's a list of those -- well, 17 is the
13 hazards. Excuse me.

14 Q. Okay. Right now, I just want to know about
15 the hazards.

16 A. Okay.

17 Q. It's all of those listed on Page 17 of the
18 report?

19 A. These are some of them. There may be some
20 listed throughout the rest of the report, too, if you
21 want -- do you need a full set?

22 Q. Yeah, I just want to know what all the --

23 A. All. Okay.

24 Q. -- the matters that you say were hazards that

1 they didn't adequately assess.

2 A. So what that means is I just have to take a
3 few minutes. It would be -- it would be this -- on
4 Table 2; plus, on Page 19, Section 2, these are
5 complaint categories. And the hazard would be mesh --
6 would be pain, infection. So I have to separate my
7 hazards from my failure modes. So I think it's -- I
8 think that I've already done that. Excuse me. I've
9 already done that, and Table 2 lists them.

10 Q. I'm sorry. I'm having a little trouble
11 following you. Are you saying that --

12 A. I'm thinking.

13 Q. -- Table 2 is a complete list of the hazards?

14 A. I'm thinking. I'm thinking.

15 Q. Okay.

16 A. It includes all of Table 2, and I have to
17 assess if there are any more throughout my report.

18 Q. Just so the record will be clear, a minute
19 ago, you called out the word "pain" and a couple other
20 words. Are you --

21 A. Right. Pain is on Table 2. That's correct.
22 It is already included.

23 Q. Okay.

24 A. So I was trying not to be duplicative.

1 Q. Okay.

2 A. Both of those were already on Table 2. The
3 other hazards, which are -- now I have to see if they're
4 also on Table 2. I think that Table 2 covers it, to the
5 best of my knowledge, in the short term, without reading
6 my whole report.

7 Q. Okay. Where on Table 2 do I look to get a
8 complete list --

9 A. On Table --

10 Q. -- of the hazards? I mean, where on Table 2
11 do you look?

12 A. Table 2 is titled "Hazard Table," and so all
13 of this table are the hazards.

14 Q. In the first column, or --

15 A. This entire table, yes.

16 Q. Okay. Now, can you give me a complete list of
17 the harms that you've opined that Ethicon failed to
18 adequately assess in the design and development of TVTO?

19 A. A hazard is a potential source of harm. So
20 now I have to go find out the harm that goes with each
21 of these. So an infection is a hazard, and associated
22 harm -- I don't think I actually talk about the
23 associated harms in this because that's generally a
24 medical opinion.

1 But, for example, if you have an
2 infection, you obviously have an associated harm with
3 it. I'm not sure I understand exactly what you're
4 trying to get to. Are you wanting me to name a harm to
5 go with every one of these hazards?

6 Q. I just wanted a complete list of the harms
7 that you're -- that you have opined that Ethicon did not
8 adequately assess.

9 A. All of them that go with -- that are matched
10 up with these hazards.

11 Q. Okay.

12 A. I have not made a statement of which harms go
13 with each and every hazard or each and every failure
14 mode.

15 Q. Okay. Let me follow up and -- for instance, I
16 know when we were asking about TVTR, I believe you
17 said -- you listed fraying, as an example, as a hazard.

18 A. That is a failure mode.

19 Q. Is that in your Table 2?

20 A. It's in Table 3, which is a list of failure
21 modes.

22 Q. Okay. Well, what is -- what is the harm, or
23 is there any harm associated with fraying?

24 MR. WALLACE: Objection; asked and

1 answered.

2 A. Okay.

3 THE WITNESS: Does that mean --

4 MR. WALLACE: Well --

5 A. I'm confused.

6 Q. (BY MR. DAVIS) I haven't asked that question,
7 but he can object. What harm do you associate with
8 fraying?

9 MR. WALLACE: Objection to form; asked
10 and answered.

11 A. If the device frays or ropes, then -- fraying
12 and roping are grouped together through all of these
13 reports. Then what happens is they can make it so you
14 have urinary retention or damage to the urethra. That
15 is published in these documents, the design history
16 file; and so I know, through review of those documents,
17 that that is a harm that's associated with that failure
18 mode.

19 Q. (BY MR. DAVIS) Okay. Then I believe you
20 said -- you listed degradation as a hazard?

21 A. Degradation -- I have to always think whether
22 it is a hazard or a failure mode. So if a device has a
23 failure mode of degradation, that can lead to a harm,
24 which is broken mesh or torn mesh.

1 Q. Okay.

2 A. Because a hazard is a potential source of
3 harm. They're related.

4 Q. Do "hazard" and "harm" mean the same thing,
5 or --

6 A. No, sir.

7 Q. Okay. So have you associated any harm with
8 degradation?

9 MR. WALLACE: Objection to form.

10 A. I just answered this. With degradation, if
11 the -- if the material degrades, then it's stated
12 throughout these documents that you can get tears, mesh
13 tears and breaks; and that's also a complaint. So, yes,
14 that is a harm.

15 Q. (BY MR. DAVIS) Can you identify just one
16 document that discusses a mesh tearing or breaking
17 inside the body after implementation?

18 MR. WALLACE: Objection to form.

19 A. I can refer to the 2002 complaint analysis.
20 Would you like me to find the Bates number to that, or
21 what?

22 Q. (BY MR. DAVIS) You're saying there's a 2002
23 complaint analysis of a torn mesh after it's been
24 implanted?

1 A. Yeah, but it's listed as a complaint; so it
2 would have to have been implanted. And if you look in
3 my report -- are we still on "O," or are we on "R"? I'm
4 confused now. I'm sorry.

5 Q. Well, whichever report you think it's in. I'm
6 talking about degradation, and you've now referred to a
7 complaint analysis in 2002. Yes, if you can -- if
8 you've footnoted that, I'd like you to identify it for
9 me.

10 A. Okay. I'm trying to find it. There's a lot
11 of pages here. It's going to take me a moment. This
12 is -- okay. Let's see here. I'm getting close.

13 So it is referred to as a 2002 letter,
14 which is -- included a complaint analysis. It's on --
15 starts on Page 20 of my TVTR report and goes to 21,
16 where it defines the 11 new hazards, one of which is
17 mesh broken; another of which is torn mesh, which can be
18 the harm associated with degradation.

19 Q. Okay. Did that complaint report, in any way,
20 shape, or form, associate the torn or broken mesh with
21 degradation?

22 A. What you asked me, is it -- was it after it
23 was implanted in a woman's body; and that was "yes."

24 Q. Okay. So it's your recollection or belief

1 that this complaint report was reporting on some mesh
2 that had been implanted inside a woman's body, and then
3 it degraded and tore?

4 A. Yes. There's evidence as early as, like,
5 19 -- actually it was, like, in 1983, the first data,
6 because I remember it was back when I was in college
7 about -- in the 1990s, about degradation. And there was
8 other data that supported the fact -- I can't tell you
9 the Bates number, put my finger on it, of this. But
10 this one definitely says that there's torn mesh, and
11 it's after it's been in a woman's body; and there's
12 broken mesh after it's been in a woman's body.

13 Q. And did you footnote that document you're
14 referring to there?

15 A. Of course I did. It is right here, 59.

16 Q. Footnote 59?

17 A. Which is back to footnote -- it's one of those
18 repeat footnotes from -- 57 was the first time I
19 footnoted it.

20 Q. Okay. And that's in your TVTR report?

21 A. Yes, sir.

22 Q. Okay. Thank you.

23 Okay. If the FDA had ever issued an order
24 making findings on the significance of degradation of

1 polypropylene in the body, would that be significant to
2 you?

3 MR. WALLACE: Objection to form.

4 What context?

5 A. Yeah, I would like to know what -- what you're
6 trying to ask. If the FDA -- I thought the FDA was not
7 within the scope of this, is what I'm trying to
8 understand.

9 Q. (BY MR. DAVIS) My question is simply: Would
10 it be something you would want to know about if the FDA
11 had entered an order making --

12 A. If I would --

13 MR. WALLACE: Objection.

14 Q. (BY MR. DAVIS) Let me -- let me finish my
15 question.

16 A. Huh-uh.

17 MR. WALLACE: Objection to form.

18 Q. (BY MR. DAVIS) Well, let me -- please let me
19 finish my question.

20 Would it be of interest to you, as part of
21 your study in this case, to know whether or not the FDA
22 has ever entered an order making findings on the extent
23 to which polypropylene degrades within the human body?

24 MR. WALLACE: Objection to form.

1 A. I'm sure it would be of interest, yes.

2 Q. (BY MR. DAVIS) Okay.

3 A. It may not have any relevance to my opinions,
4 but it would be interesting.

5 (Marked Wilson Exhibit No. 25.)

6 Q. (BY MR. DAVIS) I'm going to hand you
7 Exhibit 25. And it's a lengthy document, but can you
8 tell from just the first page that that document
9 purports to be an order on the part of the FDA?

10 MR. WALLACE: Objection to form.

11 A. I don't know if it's an order. It says it's a
12 reclassification.

13 Q. (BY MR. DAVIS) Look at the -- thank you.

14 Look at the first paragraph, under the
15 heading "Introduction" on the first page. Look at the
16 last sentence of that paragraph. Do you see where it
17 says "this order"?

18 A. Now I do, now that you pointed it out.

19 Q. Okay. So you would agree this --

20 A. Can I read the first paragraph, please?

21 Q. Sure.

22 A. Thank you, sir.

23 MR. WALLACE: You've given her a document
24 on sutures.

1 A. Right. This -- this is something about
2 sutures.

3 Q. (BY MR. DAVIS) Okay. It's about
4 polypropylene sutures, right?

5 A. Yes, sutures.

6 Q. Okay. And --

7 A. Polypropylene sutures.

8 Q. Good.

9 MR. DAVIS: And, Ed, I don't really think
10 you need to coach the witness.

11 MR. WALLACE: I'm not.

12 MR. DAVIS: Yes, you did.

13 Q. (BY MR. DAVIS) So let's follow up on this.

14 Do you have any reason to believe that
15 polypropylene in the form of a suture would degrade
16 differently from polypropylene in the form of a mesh --

17 MR. WALLACE: Objection.

18 Q. (BY MR. DAVIS) -- in the human body?

19 MR. WALLACE: Objection to form.

20 A. Where in the human body?

21 Q. (BY MR. DAVIS) In the pelvic region --

22 MR. WALLACE: Objection to form.

23 Q. (BY MR. DAVIS) -- of a female body.

24 A. It could. It could. It certainly could.

1 Q. Okay. And if you look at --

2 A. You know, I've had a lot of experience with
3 medical devices where you make assumptions; and they are
4 just faulty. Like in heart valves, people assumed that
5 changing one of the components would have -- and it was
6 the (inaudible), not the final product -- would make no
7 difference. And guess what? People started dying,
8 because, you know, you make one false assumption in one
9 dimension. And the leakage of those -- the leakage
10 rates went up. People started having blood clots. So
11 you can't just assume that one thing is the same as
12 another, in my experience.

13 Q. Did you consider Exhibit 25 as part of your
14 work in this case?

15 A. I had read it; but I didn't consider it
16 because it was on surgical sutures, not relating to the
17 mesh that was involved in the TVT.

18 Q. Okay. Do you know --

19 A. I was aware that this happened, that they were
20 Class 2 devices.

21 Q. And -- well, look at Page 7 of the order,
22 the -- look at the last paragraph on that page. Do you
23 see in that paragraph where there's a discussion of
24 oxidative degradation?

1 MR. WALLACE: What page are you on?

2 MR. DAVIS: Page 7.

3 MR. WALLACE: Where at on Page 7?

4 MR. DAVIS: The last paragraph. I'm
5 letting her read the last paragraph on the page.

6 Q. (BY MR. DAVIS) Do you see where it discusses
7 oxidative degradation of polypropylene?

8 A. I see that, sir.

9 Q. And do you see the FDA's finding?

10 A. I see it, yeah.

11 Q. That it proceeds slowly and is not deemed
12 clinically significant under most circumstances?

13 MR. WALLACE: Objection to form.

14 If you're reading from the document, you
15 probably need to read it exactly.

16 MR. DAVIS: Well, let's -- let's read it,
17 then.

18 Q. (BY MR. DAVIS) Do you see where it says,
19 quote: "The record data show that the loss of tensile
20 strength in vivo is primarily related to the oxidative
21 degradation of the polypropylene polymer," parenthesis,
22 "Refs. 4, 29, 32, 42, 43, and 44," close parenthesis,
23 "and that the polymer's degradation proceeds slowly and
24 is generally not considered clinically significant under

1 most circumstances of use," parenthesis, Refs. 1, 4, 42,
2 121, and 149," close parenthesis, unquote.

3 Did I read that correctly?

4 A. But you also missed part of this, which
5 says -- you know, the first sentence was neglected,
6 which it also says "surgical suture in certain
7 applications." So from this, I can't make an inference
8 whether this is directly related to the TVT products in
9 my report.

10 Q. Well, have you taken the time to look at any
11 of the reference materials that --

12 A. No, sir.

13 Q. Okay.

14 A. The FDA is outside the scope of this report.
15 I did not refer to every little reference in this when
16 it didn't have anything to do with the products I was
17 opining about. My goodness.

18 Q. Now, in your reports, let's take a -- well,
19 TVTS. For TVTS, did you opine -- well, what hazards did
20 you opine Ethicon failed to properly or adequately
21 assess?

22 A. Okay. Let me shift gears and get to "S,"
23 please. Where is it? Is "S" in here?

24 Q. It's Exhibit No. 4, if you want to look at it.

1 A. Okay. It should be -- it should be "C."

2 MR. WALLACE: No, it's -- I think it's --
3 it might be the first one here. I think it's "B."

4 THE WITNESS: Oh, no wonder I got
5 confused.

6 A. Okay. So what was your question, again?

7 Q. (BY MR. DAVIS) Can you simply please list the
8 hazards that you've opined that Ethicon failed to
9 properly assess for TVTS?

10 A. I see a lot of failure modes. I'm trying to
11 see if I actually opined on hazards. So please give me
12 a moment.

13 So on Page 16, I talk about susceptibility
14 to in vivo degradation; stiffness; improper warnings;
15 tensioning, improper tensioning; improper learning
16 curve -- that's a hazard because you don't install it
17 right -- and the inability to remove the device. Those
18 are hazards.

19 Q. Okay. What harms have you opined that Ethicon
20 failed to properly assess relating to TVTS?

21 A. Okay. So the harms related to failure modes
22 are bleeding, bladder perforation, or hematoma --
23 hematoma. Those harms are related to inserter not
24 maintaining contact. This is on Page 14. Infection,

1 urinary retention or obstruction.

2 Q. Is that it?

3 A. That's all I can see right at this minute.

4 Q. Okay. Back to TVTR. Have you --

5 A. Are we done with this for a minute?

6 Q. Right now, I'm back to TVTR.

7 A. Okay.

8 Q. For TVTR, have you opined that Ethicon did not
9 adequately assess the severities of any of the harms
10 that you've listed?

11 A. That's clearly called out in my "O" report
12 because it --

13 Q. Well --

14 A. Please let me finish my sentence.

15 MR. WALLACE: You interrupted her answer.

16 MR. DAVIS: No, wait a second. Counsel,
17 you told me not to --

18 MR. WALLACE: No, you interrupted her
19 answer.

20 MR. DAVIS: You said we've got to do one
21 report at a time.

22 A. And you didn't. You asked me one question on
23 the "S," and now you're back to "R," and I'm --

24 Q. (BY MR. DAVIS) I'm back to "R."

1 A. -- trying to answer your question.

2 MR. WALLACE: Let her answer the
3 question.

4 MR. DAVIS: Okay.

5 MR. WALLACE: If you don't like the
6 answer, that's too bad.

7 MR. DAVIS: No. I don't like the time.

8 Q. (BY MR. DAVIS) My question is about --

9 A. That's not my fault.

10 Q. -- TVTR.

11 MR. WALLACE: Well, it --

12 Q. (BY MR. DAVIS) Answer my question about TVTR.

13 A. I am.

14 MR. WALLACE: You know what? We have an
15 agreement in place and a court order. The bottom line
16 is, if you don't like her answer, ask her a different
17 question.

18 A. Here, the reason I'm not answering it --

19 Q. (BY MR. DAVIS) No, I'm withdrawing that
20 question --

21 A. -- is because they used TVT -- our data for
22 "O," it happens to be placed in there. Okay? Because
23 they didn't do their own stinking system analysis, I
24 have to rely on it in a different place. That's the

1 problem. I keep saying it.

2 Q. (BY MR. DAVIS) Please just tell me the harms
3 for which you believe Ethicon did not properly assess
4 the severity --

5 A. Absolutely.

6 Q. -- for TVTR.

7 MR. WALLACE: One thing. Are you done
8 giving your answer to the last question? Because you
9 were --

10 A. No, I haven't even answered the question
11 because I have to find it when you change topics on me
12 every question. I have a whole table on that, and it
13 happens to be --

14 MR. WALLACE: Do you want to withdraw the
15 question?

16 MR. DAVIS: No.

17 A. It happens to be Table 2, Page 17, TVTO, where
18 it clearly shows the TVTR severity ratings and how they
19 were inconsistently applied over time.

20 Q. (BY MR. DAVIS) Okay. Now, my question
21 stands. I want you to give me a complete list of all
22 the harms which you believe Ethicon failed to properly
23 assess the severity level. Have you given me a complete
24 list now?

1 MR. WALLACE: Objection to form; asked
2 and answered.

3 A. I've given you a list that I thought was most
4 important. This is not a complete list of everything
5 over the 10 or 15 years of documents. These are
6 representative of the most important things I found.

7 Q. (BY MR. DAVIS) Okay. Now --

8 A. And there's no way I can go back and complete
9 a list in this time frame.

10 Q. For TVTR, did you opine that there were some
11 frequencies of harms that Ethicon failed to properly
12 assess? If so, what are they? What are those harms?

13 MR. WALLACE: Object to form.

14 A. You're -- could you clarify your question?

15 Q. (BY MR. DAVIS) I'll be happy to.

16 With respect to the TVTR product, did you
17 opine that Ethicon failed to properly assess any of the
18 frequencies relating to any of the harms that you've
19 listed?

20 MR. WALLACE: Objection to form.

21 A. I don't recall discussing the specifics of the
22 frequencies. That's why I have to look at it. I talked
23 about the severities and the inconsistencies and that --
24 I did, and how the occurrence was changed without any

1 medications. Do I need to find that in my report?

2 Q. (BY MR. DAVIS) No, you don't -- I don't need
3 to know the page number of the report if --

4 A. Okay. Yes, I did.

5 Q. Okay. Now, you've opined that the FMEA is a
6 living document, correct?

7 A. That it should be.

8 Q. Okay. Can you show me or just identify for me
9 a standard that requires an FMEA be a -- what you've
10 described as a living document?

11 A. Are you talking about these -- their internal
12 procedures?

13 Q. We're going to break it down. I asked you
14 first about industry standards.

15 A. Uh-huh. Do you, in your pile, have
16 13485:2003, maybe?

17 Q. I'll be happy to hand you 13485. I think I've
18 got it somewhere here. Let's see.

19 (Marked Wilson Exhibit No. 26.)

20 Q. (BY MR. DAVIS) I've got one copy of it for
21 now, 26. Exhibit 26. Is that -- is that the document
22 you were wanting to see?

23 A. Yes. We should look at Section 7.1. So if
24 you look at 7.1, the italicized note, it states: "The

1 organization shall establish documented requirements for
2 risk management throughout product realization. Records
3 arising from risk management shall be maintained."

4 Q. Okay. Is there any other written standard
5 anywhere that you're relying on for your opinion that
6 the FMEA is a living document?

7 A. First you said, "Find me one," and -- yes.
8 Give me 14971. It's probably in there.

9 Q. Well, you've got it right in front of you.

10 A. Oh, okay.

11 Q. It's an exhibit already.

12 MR. WALLACE: Which number is it?

13 THE WITNESS: I bet it's 12.

14 MR. DAVIS: It's Exhibit 12.

15 THE WITNESS: And 14.

16 A. Yes. In the "Scope," it says you have to --
17 these standards "are applicable to all stages of the
18 life-cycle of a medical device."

19 Q. (BY MR. DAVIS) And you're reading from which
20 section?

21 A. Section 1 in the "Scope."

22 Q. Okay. Of Exhibit 12, correct?

23 A. Correct.

24 Q. Okay. Is there any other provision of any

1 standard, industry standard, that you're relying on for
2 your opinion that the FMEA is what you call a living
3 document?

4 A. I'm sure it's also in other sections. Would
5 you like me to check each section?

6 Q. Well, do you know of any?

7 MR. WALLACE: Object to form.

8 A. I'm sure it's in here somewhere, another
9 section.

10 MR. WALLACE: Take your time.

11 A. Because "life cycle" means all phases of the
12 life of a medical device from initial concept to final
13 decommissioning and disposal.

14 Q. (BY MR. DAVIS) Okay. Let me ask you this:
15 Explain what you -- for the court what you mean by a
16 living document.

17 A. That means that it's continuously updated as
18 new information comes in, just like their procedures say
19 that you'll evaluate complaints and update the documents
20 as appropriate, as the product goes through its life
21 cycle. So if you find that you're having a change in
22 expectations or you're having more complaints or
23 unexpected results, then you would go back and you would
24 look.

1 If you had done a risk assessment, you
2 would look at those and say, "Oh, we missed something,"
3 or, "Jeez, we didn't do a system-level risk assessment;
4 so we'd better" -- "we'd better go look at that. Our
5 assumption was false that we relied on in previous -- in
6 previous documents." So that's what it means.

7 Q. If a post-market review indicates that you're
8 getting complaints, but they're within the levels that
9 you expected, anticipated in your FMEA, are you
10 saying -- would you go back and then do an update to
11 your FMEA?

12 A. Yeah, totally. You can't rely on that.
13 Because what I saw Ethicon do is they set the bar so
14 freaking high -- 294, or something like that -- that
15 nothing would -- nothing would hardly exceed -- I mean,
16 that is just like -- you would have to have something
17 catastrophic -- and this is clearly in my report, that
18 you'd have to have something with very high frequency,
19 very high -- a serious injury with no warning, or
20 catastrophic, nearly, and unable to detect it.

21 So if you set the bar, as a
22 manufacturer -- which I told you earlier that each
23 manufacturer sets their own threshold. If you set that
24 threshold so high that your expectations are so low,

1 that's where you go out and you say, "Whoa, does this
2 even make sense? What are other people saying?" Or you
3 find out that doctors are complaining, and peer-reviewed
4 articles, which I also talked about. So you can't just
5 say that, no. That's not a true statement.

6 Q. Okay. In connection with your opinion --

7 A. Do you want me to finish your prior question
8 about where else in the standard it says you have to do
9 it throughout the life cycle?

10 Q. No.

11 A. Okay.

12 MR. WALLACE: So you withdrew the
13 question?

14 Q. (BY MR. DAVIS) Tell you what. I'll withdraw
15 the question because I'll challenge your counsel at the
16 appropriate time to show the court where it says that.
17 So I'll worry about --

18 MR. WALLACE: The bottom line is you're
19 not letting her finish her answer.

20 MR. DAVIS: Well --

21 MR. WALLACE: She asked if you wanted her
22 to finish her answer --

23 MR. DAVIS: No, I don't want to waste
24 any --

1 MR. WALLACE: -- and you said, "No, I
2 don't want you to finish your answer."

3 MR. DAVIS: No. Can we move on?

4 MR. WALLACE: So there's no challenge
5 here. You waived any right you have to any challenge,
6 Paul.

7 MR. DAVIS: I've already withdrawn the
8 question. Please quit wasting my time.

9 MR. WALLACE: Well, you're not going to
10 sit here and say what the court's going to do or not
11 going to do.

12 MR. DAVIS: No.

13 MR. WALLACE: The judge is going to make
14 up his own mind based upon the fact that you didn't let
15 her answer the question.

16 MR. DAVIS: Absolutely. And I've
17 withdrawn the question. That question is out. So let's
18 move on, please.

19 MR. WALLACE: Fair enough, then. Go
20 right ahead.

21 Q. (BY MR. DAVIS) Now, can you identify -- or
22 let me ask this: Did you apply any generally accepted
23 standard in your evaluation that led you to believe that
24 Ethicon has set its requirements too high?

1 A. What I applied was 30 years of experience
2 doing this and helping many, many companies in -- of
3 implantable devices set up their risk analysis, and the
4 CEOs and the clinicians I work with on a frequent basis,
5 all of those things, and the design teams. I applied my
6 knowledge, expert knowledge, to make that assessment.

7 Q. So answer this question, please: Did you
8 apply any generally accepted written standards in making
9 your analysis that Ethicon set its standards too high
10 for its -- for its risk to be unacceptable?

11 A. I did apply the principles of 13485 and 14971.

12 Q. Okay. Does --

13 A. And the MedDev for the post-market
14 surveillance.

15 Q. Okay. You're referring to the MedDev
16 12-point --

17 A. I'd have to look up the number, but it's in my
18 report.

19 Q. Okay. Well, just -- well, you only cited one;
20 so I'll rely on that.

21 A. Yeah, exactly.

22 Q. Okay. So -- okay. Do you have any other
23 source for a written industry standard to support your
24 opinion that Ethicon set its risk numbers too high?

1 MR. WALLACE: Objection to form.

2 A. I think I've named industry standards, my own
3 experience, and multiple device companies. So that
4 pretty much covers it.

5 Q. (BY MR. DAVIS) Okay. Can you explain for the
6 court Ethicon's system that generated the number 294?

7 A. I have no idea, and I believe I put that in my
8 report. But I do know that the only way you can result
9 in that high of a number is if you look at the -- just
10 look at the combinations. You have to have a 9 or a
11 10 -- I mean, to get to 294, you'd have to have a 10 by
12 a 10 by a 3, at least, you know.

13 Q. Okay.

14 A. So you have to have some highly severe,
15 frequently occurring -- something that's not easily
16 detected, or some combination thereof, to get that high
17 a number.

18 (Marked Wilson Exhibit Nos. 27 and 28.)

19 Q. (BY MR. DAVIS) Let me hand you Exhibit --

20 A. Or something that you -- you know, it's pretty
21 high.

22 Q. Let me hand you Exhibit 27. Do you recognize
23 that exhibit?

24 A. I certainly do.

1 Q. And you opined about this exhibit, didn't you?

2 A. Yes, sir.

3 Q. And what were your -- can you give me an
4 overview of your criticisms of Exhibit 27?

5 A. Well, first off, this is a Design FMEA that
6 was done five to seven years after the design was
7 frozen. So it's a total retrospective analysis, where
8 the intent of a DFMEA is to start with concept phase;
9 and it's listed in the standards and Ethicon's
10 procedures as to be done in the design input phase. So
11 that's number one, is that it's sort of "too little, too
12 late," because you're supposed to do these things, you
13 know, often, frequently, not "too little, too late."
14 And so that's -- that's my first opinion.

15 Second, it's -- there's a table in my "R"
16 report, I believe. Maybe it's the -- that talks about
17 this as like -- I couldn't -- I didn't even, you know,
18 pay attention to it at first, because it says things
19 like "not imaginable," which is not something I'd ever
20 seen before. And if you go to my R report, it talks
21 about just the contradictions, omissions, things like
22 that in this FMEA.

23 But, most importantly, it's five to seven
24 years after; and it didn't even jive (sic) with or have

1 any communication with the complaint system. So it's
2 way out of sync.

3 Q. Okay. But, now, you said an FMEA is a living
4 document. You should be doing new FMEAs throughout the
5 life cycle.

6 A. You should start a design -- in the design
7 phase so you can design out the defects. That is the
8 number-one thing to do to prevent hazards from getting
9 to the field and causing harm.

10 Q. Okay.

11 A. It's starting at the design phase. And they
12 didn't do that.

13 Q. Are you saying that you believe Ethicon was --
14 should not have tried to do a risk assessment in 2001
15 for TVT?

16 A. That's not at all what I'm saying. Listen,
17 please. I'm saying that they didn't do it during the
18 design phase of the device, which was much more in 1995,
19 not in 2001. The design has to be -- you can't design
20 out any risks or potential sources of harm if, in fact,
21 you haven't done any analysis. And there was not.

22 Q. So my question today, though, now, is: What
23 imperfections do you see in this risk assessment itself?

24 A. It's in the report, and that was my first

1 answer.

2 Q. Okay.

3 A. That was my answer to your -- an answer to
4 your question.

5 Q. Okay. It's all in your report?

6 A. That -- that was not in my report. I started
7 with that. I believe that was somewhere in the "O"
8 report. But if you want to look at this design
9 document -- look at Page 17, some other factors,
10 additional factors, that I think are wrong with this
11 document.

12 Q. Okay.

13 A. Look at Page 17 of the "R" report.

14 Q. That would be fine. Thank you. Okay. So let
15 me ask you --

16 A. It starts, actually, on Page 16 and starts
17 with a listing of what's wrong with this retrospective
18 report.

19 Q. Okay. Now, what industry standard did you
20 apply in evaluating Exhibit 27?

21 MR. WALLACE: Objection to form.

22 A. Well, this clearly says it was done to 1441.
23 So I looked at 1441 and --

24 Q. (BY MR. DAVIS) Okay.

1 A. -- ISO 9001 and EN 46001, which were the
2 applicable standards at the time that this was
3 performed.

4 Q. Okay. And did you apply any company standards
5 in assessing Exhibit 27?

6 A. Absolutely. I looked at the SOPs.
7 PR 602.003, OP 650-010 and -011, I believe, are the
8 applicable ones in my report.

9 Q. Why did you choose those?

10 A. Because those are the ones that were relevant.

11 Q. Okay. What was your basis for believing those
12 were the relevant ones?

13 A. Well, let's look at them. Number one -- okay.
14 So the OP -- the PR 602.003 is entitled "Procedure for
15 Medical Device Risk Management." So that would be
16 appropriate to risk management. And it talks about a
17 systemic risk management process using a DDSA.

18 Q. Okay.

19 A. They didn't use a DDSA. But then 650-010
20 talks about risk management again, and 611 (sic) talks
21 about DFMEAs --

22 Q. Okay.

23 A. -- 650-11 -- excuse me -- "Operating Procedure
24 for Design Failure Mode and Effect Analysis."

1 Q. Did you make any effort to find out which
2 company facilities those procedures applied at?

3 A. I did, yes, sir.

4 Q. Why? Why did you try to do that?

5 A. Well, because if you look -- I wanted to find
6 out which revisions were appropriate at the time it was
7 done.

8 Q. Okay.

9 A. And if you look at the revision history for
10 these documents, it tells you, like, when it tries to
11 roll out at each facility. And so I tried -- although
12 they changed computer systems somewhere along the line,
13 it was very challenging to actually determine on what
14 exact day, because these projects would start; and
15 sometimes, when the procedures rev-bumped -- and I'm
16 quite sure that's in Dan Smith's testimony, also, that
17 once these procedures rev-bumped, the design teams
18 didn't always rev-bump with them.

19 Q. Okay.

20 A. So I looked at that in quite a bit of detail.

21 Q. Okay. Yeah, I think -- did you just -- you
22 just referred to looking at the revision histories. Is
23 that an example of the type of document that you looked
24 at, Exhibit 28?

1 A. It has similar information on it. It just
2 doesn't have the same format of the one, because I don't
3 think I have the archived document. I think I have the
4 full.

5 Q. Well, you see that Exhibit 28 for procedure
6 PR 602.003 -- it actually shows you which locations the
7 procedure applied at.

8 A. Let me take a look. I see that.

9 (Marked Wilson Exhibit No. 29.)

10 Q. (BY MR. DAVIS) And the same thing.
11 Exhibit 29 relates to --

12 A. But let's go through each revision, because it
13 can change. This is Version 1, which was 981099. This
14 is 2001. This is Version 2, Version 3. And this was
15 conducted in Germany, so I couldn't find any procedure
16 that was in English or -- or any procedure that said --
17 other than these, that said how you're supposed to do
18 FMEAs.

19 (Marked Wilson Exhibit No. 30.)

20 Q. (BY MR. DAVIS) Okay. And I'm handing you
21 Exhibit 30. That would be for, I think, Exhibit -- for
22 procedure OP 650-011, correct?

23 A. Right. And if -- if they're -- these are just
24 saying when they rolled them out. That doesn't mean

1 that corporate doesn't apply to the rest of the
2 corporation. This just says when they're rolling them
3 out at certain facilities, not when -- that corporate
4 doesn't apply to the corporate holder for design
5 controls.

6 Q. Have you seen any document that indicated that
7 Exhibits 28, 29, or 30 -- that those procedures in those
8 three exhibits applied in Germany at Neuchâtel?

9 A. That's Switzerland, isn't it?

10 Q. I'm sorry. It applied in Germany or
11 Switzerland?

12 A. I must say that those documents, if they're
13 the corporate person in charge of design control, then I
14 did make the assumption that the corporate procedures
15 applied. So Ethicon GmbH in Germany was the corporate
16 design control representative for this document; and it
17 was stated as such in the DHF, the remediated DHF that
18 occurred five years after.

19 So when they transferred from Sweden and
20 to -- and Sweden, which was -- when they transferred the
21 corporation to Germany and the manufacturing to
22 Switzerland, that's when the corporate responsibility
23 for design control switched to Germany. And that's why
24 I used these corporate documents.

1 (Marked Wilson Exhibit No. 31.)

2 Q. (BY MR. DAVIS) Let me hand you Exhibit 31.

3 A. Okay.

4 Q. Is Exhibit 31 one of the risk analyses that
5 you opined on?

6 A. Did we finish that last question?

7 Q. If you have more to say, you're free to -- I'm
8 not trying to interrupt you. I thought you were
9 through.

10 A. I thought you wanted me to -- know everything
11 wrong with this. Okay. I had a whole table on that,
12 of -- I just wanted to point that out. I don't think we
13 ever got to my answer on that, that this whole table on
14 Page 17 talks about how this design FMEA, which was
15 retrospective, is faulty, in my opinion, because it has
16 things like "not imaginable" when they clearly have
17 documentation that it was -- it was not only imagined,
18 but, for example, said wrong mesh composition.

19 Well, not imaginable, yet they measured
20 the IR spectra. They had a material spec. They didn't
21 look at post-market data. They had contradictions and
22 omissions, and then they -- failure to perform its
23 function. So there were quite a few things that led me
24 to believe that this was just not a trustworthy

1 document. Much more like it was just, "Oh, my God.

2 It's five years later. We'd better whip one of these
3 out."

4 Q. Are you through?

5 A. Yeah, I am now.

6 Q. I've handed you Exhibit 31.

7 A. Okay.

8 Q. You opined on this risk analysis, didn't you?

9 A. I don't even know what product it is yet, sir.
10 You said TVTO. So let me go to the "O" and think about
11 this. I've got my "O" report. And if it's listed, then
12 I should have opined about it. Oh, yeah.

13 Q. So my question is: Look at -- in the -- on
14 the -- any one of the pages. Do you see the header at
15 the top of the page, upper left-hand part of the page --

16 A. Yeah.

17 Q. -- that shows a reference to PR 602-003,
18 Appendix 1?

19 A. 2, but correct. It's Appendix 2.

20 Q. Well, you see it actually says Appendix 1?

21 A. Well --

22 Q. Well, it depends on which page -- depends on
23 which page you're looking at, right?

24 A. I was looking at the page number that ends in

1 447 down here in the numbers. So --

2 Q. Okay. The bottom line is: You understand
3 Ethicon's practice of, when they're filling out one of
4 these risk analyses, they reference the fact that
5 they're using a form from one of their company
6 procedures?

7 A. Yes. Yes.

8 Q. And so it shows the Appendix 1, Appendix 2,
9 et cetera, here?

10 A. Uh-huh.

11 Q. Okay. Now, back to the -- that 2001 risk
12 analysis -- I believe it was Exhibit 27 -- look at the
13 second page of that exhibit. You see in the upper
14 left-hand corner of the second -- of the second page of
15 the document, they have a header that says
16 "Anhang 4-02/3"?

17 A. Yes.

18 Q. Did you take the time to -- well, did you
19 realize that that's in German?

20 A. Well, I know it's German.

21 Q. Okay. And how did you know it was German?

22 A. I took German three years in high school.

23 Q. Okay. And did you -- do you know what
24 "anhang" means?

1 A. I have no clue.

2 Q. Did you take the time to look it up?

3 A. I did not Google it.

4 Q. Okay. You do realize it's easy to Google it
5 and -- you can type in the name, and they'll give you --

6 A. I know that.

7 Q. Okay.

8 A. I just didn't Google that word, no. I looked
9 at it, that it was per EN 1441, which was the standard
10 in place at the time.

11 Q. And would it surprise you that "anhang" means
12 'appendix'?

13 A. What do you know? I don't know. I guess it's
14 a surprise to me, yes. You know, I was analyzing the
15 document, not translating German.

16 (Marked Wilson Exhibit No. 32.)

17 Q. (BY MR. DAVIS) Let me hand you Exhibit 32.

18 A. Okay.

19 Q. Have you ever seen this document before today?

20 A. You know, unless it was translated to English,
21 I don't. But I'd be glad to take a look at any English
22 translation.

23 Q. Okay. Do you recall seeing it in German?

24 A. I just -- no, I haven't seen this in German.

1 Q. Okay. That's fine. Have you seen this
2 document in English?

3 A. I don't know. I just answered that, sir. I
4 said unless I've seen it in English, I wouldn't know.

5 MR. WALLACE: Do you have an English
6 version for her?

7 MR. DAVIS: I've already handed it to
8 her. She's got it in front of her.

9 A. This is German.

10 Q. (BY MR. DAVIS) Well, you've got to look past
11 the first couple pages.

12 A. Oh, okay.

13 MR. WALLACE: Well, it's about a 40-page
14 document; so she's going to take the time to read it.

15 Q. (BY MR. DAVIS) No, all I want to know is:
16 Have you seen this document before?

17 A. I don't know yet. I'll look. I'll look.

18 MR. WALLACE: All she's seen is German
19 language, Paul.

20 THE WITNESS: Sorry.

21 MR. WALLACE: Give her the time, man.

22 THE WITNESS: I'm at Page 13, and it's
23 still German.

24 MR. WALLACE: Okay. So you've looked

1 past the first page, right?

2 THE WITNESS: 17 pages, still in German.

3 Q. (BY MR. DAVIS) Okay.

4 A. So it does look like, on Page 18 of 23, that
5 it starts in English. And I do not recall seeing this
6 document.

7 MR. WALLACE: Why don't you take the time
8 to read it?

9 THE WITNESS: I'd be glad to.

10 Q. (BY MR. DAVIS) Do you feel like you need to
11 read all 20 or 30 pages in order to know whether you've
12 seen it before?

13 A. Well, it would only be Pages 18 to 23 --

14 Q. Okay.

15 A. -- because that's where the English starts,
16 right?

17 Q. If you feel --

18 A. I just said that.

19 Q. If you feel like you need to read --

20 A. Are you going to ask me questions about this?

21 Q. No, I've already asked all I want to ask about
22 it.

23 A. Well, I can't tell yet if I've read this
24 document. So --

1 Q. Okay. Take whatever time you need.

2 MR. WALLACE: Are you going to reserve
3 any time for after I get done, Paul?

4 MR. DAVIS: We'll see.

5 A. I do not believe I saw this document.

6 Q. (BY MR. DAVIS) Okay.

7 A. It doesn't mean I -- I just don't recall ever
8 seeing this document.

9 (Marked Wilson Exhibit No. 33.)

10 Q. (BY MR. DAVIS) Let me hand you Exhibit 33.
11 Have you ever seen that exhibit before today?

12 A. From 2008? You know, I think I've seen this
13 section -- this format in Section 3.2, because they use
14 this long -- I mean, it matches. This attachment
15 matches the format in this.

16 Q. Did you opine on Exhibit 33?

17 A. No. It's not referenced anywhere in my
18 documents or in my reports, I don't believe.

19 Q. Okay.

20 A. I did reference this document.

21 Q. When you say this -- what document are you
22 referring to?

23 A. The DFMEA done five or seven years after the
24 design was complete.

1 Q. Just so the record is clear, give me the
2 exhibit number.

3 A. This would be Exhibit No. 27.

4 Q. Okay.

5 A. Looks like the format follows the format in
6 the attachment, but I didn't opine on Attachment 33.

7 Q. And I understand --

8 A. It's for any mesh, and it's for certain pad
9 sizes. So, you know, I just didn't --

10 Q. Well, I understand the format is similar to
11 Exhibit 27. My question is: Have you ever seen
12 Exhibit 33 before today?

13 A. I don't recall.

14 Q. Okay.

15 MR. DAVIS: I'll reserve the rest of my
16 questions -- my time.

17 MR. WALLACE: So you're done?

18 THE WITNESS: May I take a momentary
19 break?

20 MR. WALLACE: Yeah. Let me -- so you're
21 done?

22 MR. DAVIS: Well, it depends on what I
23 hear you ask.

24 MR. WALLACE: Subject to what I ask, do

1 you have any amount of time --

2 MR. DAVIS: Yeah.

3 MR. WALLACE: Okay. Why don't we take a
4 break?

5 MR. DAVIS: Keep a record of how much
6 time I've got left, please.

7 THE REPORTER: Yes.

8 (Break from 1:05 p.m. to 1:17 p.m.)

9 E X A M I N A T I O N

10 BY MR. WALLACE:

11 Q. Ms. Wilson, I have a few questions for you.

12 Okay?

13 A. Okay.

14 Q. You were asked some questions earlier about
15 CERs, or clinical evaluation reports, or clinical
16 evidence reports. Do you recall that line of
17 questioning?

18 A. Uh-huh.

19 Q. Is it fair to say, as part of your job as a
20 consultant to medical device companies, that you
21 consider CERs?

22 A. Yes.

23 Q. And can you tell me: Did you consider CERs in
24 the context of providing your reports in these cases?

1 A. Yes, I mean, we consider that because
2 that's -- we consider that and what the clinicians say.
3 For example, we use doctors, marketing people,
4 clinicians at the start of the risk management process.
5 And, you know, then, if the risks -- about the
6 risk/benefit analysis, I also spoke about that. If, at
7 the end, there's high risk, you go back and use those
8 clinicians or, you know, a group of them, to say, "Does
9 the risk outweigh the benefit?"

10 And then they rely on the literature and
11 other things to help perform that. So, yes, as part of
12 my job, I've done that on a number of occasions.

13 Q. Well, you mentioned a number of times just
14 now, and during your deposition, that you're not a
15 medical doctor; but you work with clinicians. Can you
16 give me, say, a real-life example of where you've worked
17 with clinicians as part of a team when there has been a
18 product that has had problems?

19 A. Actually, there's several of them; but one of
20 them was a knee -- was a knee implant, and there was a
21 rash of infections. And I was the consultant for them
22 in the R&D design control process, and I did a ton of
23 risk management with that team. But all of a sudden,
24 they had a rash of infections; and, of course, everyone

1 wants to blame the user, you know, the doctors, or try
2 to figure it out.

3 So what we did is we formed a team
4 immediately, like, overnight, and got the head of all
5 the departments and the VPs involved and clinicians
6 involved; and we opened up a kappa. We opened up a --
7 you know, a complaint investigation and tried to figure
8 it out. Brought devices back from the field. Brought
9 similar lot numbers back to see if there was, in fact, a
10 manufacturing failure. And it worked out -- it turned
11 out that there was a design defect in the mating parts.

12 Q. In the what parts?

13 A. The mating parts. That's what I was trying to
14 get across, that you can't look at each part
15 individually, because it was in the analysis that they
16 found out that there wasn't enough room between the
17 mating parts, that if there was any sort of problem, the
18 infection just grew and grew and grew.

19 Q. And were you working with actual clinicians in
20 connection with that?

21 A. Right. We were working with the clinicians,
22 the doctors at the hospital, the hospitalists. We
23 worked with the regulatory folks, meaning the regulatory
24 folks who had to pull the product back. We worked with

1 the design engineering and marketing team, the design
2 engineers -- you know, quality. It was -- it was a
3 pretty big effort. That's what you'd expect to see if
4 there's something going on.

5 Q. So even though you say you're not a doctor,
6 you have to understand a device and the potential risk
7 with the device so that you can work and direct --

8 A. Right. Another example is I would sit there
9 and do, side by side with the doctor, the failure mode
10 effect analysis. I'll just take a whole afternoon and
11 go, you know, "What could go wrong?" "Well, it could
12 hit this nerve." "Okay." Then we go side by -- you
13 know, step by step by step. The doctors don't know how
14 to do the risk analysis, but they can tell me what the
15 harm is associated with failure mode.

16 Q. Let's move on to the FDA. Do you recall being
17 shown certain documents, including guidance and letters
18 from the FDA?

19 A. Uh-huh, yes.

20 Q. Are you able to offer -- first of all, are you
21 able to offer the opinions in your reports in the Wave 1
22 cases without reliance on documents from the FDA?

23 A. Absolutely.

24 Q. And why is that?

1 A. Well, first off, the international standards
2 and the -- first, I've worked in this for 30 years; so I
3 really feel like that's why I can do this as an expert.
4 I've done it for a lot of companies which are both
5 international -- which are international; and,
6 furthermore, they're aligned standards.

7 Q. Okay. Let me show you a particular exhibit,
8 Exhibit 25. It's a -- it's called an order or a letter.
9 Can you tell me the date at the top of it?

10 A. Yeah. It's way back in 1990.

11 Q. Okay. And in Exhibit 25, you were asked about
12 degradation. Do you recall that line of questioning?

13 A. Yes, I do.

14 Q. And you were asked to look at the first
15 paragraph on Page 8. Do you see that?

16 A. Yeah.

17 Q. Or -- I'm sorry -- the last paragraph on
18 Page 8.

19 A. Oh, yeah. Back here.

20 Q. Why don't you take a look at the rest of the
21 paragraph, which actually goes on to Page 9, and tell me
22 whether or not you actually think this document supports
23 your opinion that the -- where the device may be
24 implanted in its intended use is critical.

1 MR. DAVIS: Object to the form.

2 A. Let me see if I understand this. Well, first
3 I'd have to look at these references, but -- to know.
4 But what it's telling me is that you have to look --
5 wait a minute. You have to look at where the various
6 sites are, how the healing is done, and look at the
7 methods.

8 You can't just apply this universally --
9 and that's what I was really trying to say -- ahead of
10 time. You can't take a tensile thing, a tensile --
11 sorry -- a suture test done in 1990 and apply it
12 universally to other places.

13 Q. (BY MR. WALLACE) And you believe that's
14 actually supportive of that opinion that you have to
15 consider where the device might be and its intended use,
16 right?

17 MR. DAVIS: Object to the form.

18 A. Well, that's -- yeah, that's what I said
19 originally, too. I just want to make sure I'm on the
20 right --

21 Q. (BY MR. WALLACE) You are.

22 A. -- page. Because here it talks about
23 inflammatory response. I mean, you have to evaluate it
24 not in a vacuum. You have to look at the risks in

1 various actual -- it says even at any given wound site.

2 You can't just apply it "one size fits all."

3 Q. Thank you.

4 Now, you were asked some questions earlier
5 about ISO standard 10993. Do you recall being asked --

6 A. Yes, I do.

7 Q. -- a lot of questions about that?

8 A. Uh-huh.

9 Q. And you indicated at some point that -- with
10 respect to whether or not you were an expert with some
11 of the testing. Do you recall, generally, that line of
12 questioning?

13 A. Yeah, yes.

14 Q. Are you an expert when it comes to risk
15 assessment of the biocompatibility standards enunciated
16 in 10993?

17 A. Yes. I mean, I look at the risk assessment
18 portion of it; but I don't actually perform the tests.

19 Q. So, in other words, you're not actually the
20 microbiologist that would go out and talk to the company
21 about doing a cytotoxicity test?

22 A. I'm not the microbiologist, but I've been --
23 we've done -- I'm very familiar with it. We had to do
24 lot-by-lot cytotox testing in -- like in the heart

1 valves, for every single -- I've had to qualify
2 cytotoxicity measurement devices in my experience, in
3 water systems, for cytotoxicity and things like that.

4 But I don't -- and we tell companies, "You
5 should do this test, this test, this test, per
6 ISO 10993, Part 1." But what I was referring to is the
7 fact that I don't actually go out there and, you know,
8 do the tests.

9 Q. You're not the laboratory --

10 A. I'm not the lab.

11 Q. -- that would be hired --

12 A. Right.

13 Q. -- to do the test?

14 A. Right. So maybe I misunderstood.

15 Q. But is it fair to say that you understand the
16 risk assessment and the -- and the various tests under
17 10993 --

18 A. Yeah, I mean --

19 Q. -- in connection with your practice?

20 A. Yeah.

21 Q. You were asked a number of times during the
22 deposition whether or not a list was complete or not,
23 and you wanted to consult your report. Do you -- do you
24 recall, a number of times, being asked those types of

1 questions?

2 A. Yes.

3 Q. Okay. Is it fair to say that all of the
4 opinions that you have to offer in these cases are
5 contained in your reports?

6 A. My reports state my opinions. That's not a
7 problem. That's not an issue. But when the question
8 was are they the universe of harm, you know, my report
9 says the important things.

10 Q. And you were given some documents that it was
11 unclear whether or not you had seen them before.

12 A. Yes.

13 Q. Do you remember that?

14 A. Yes.

15 Q. Are you willing to consider any additional
16 facts or data, even if they may not support your
17 opinions?

18 A. Sure. And I even said I would be glad to take
19 a look at those and review them. I'm quite sure that
20 was on my -- on the record already.

21 Q. Okay.

22 MR. WALLACE: I have no further
23 questions.

24 *

1 E X A M I N A T I O N

2 BY MR. DAVIS:

3 Q. Just a couple follow-ups.

4 Am I still correct: You did not utilize
5 ISO 10993 in connection with your work on this case, did
6 you?

7 A. I did review -- I answered that question, that
8 I reviewed a risk assessment related to 10993. What I
9 believe I also said is I did not go back and perform a
10 gap analysis to that standard to make sure that
11 everything was -- you know, the T's were crossed and the
12 I's were dotted.

13 Q. Does ISO 10993 address degradation?

14 A. I assume the 10993 does address any
15 products (sic) of degradation. There's a test in there.

16 Q. Does it address oxidative degradation?

17 MR. WALLACE: Objection to form.

18 A. I don't know, off the top of my head.

19 MR. DAVIS: That's all I have.

20 THE REPORTER: Read and sign?

21 MR. WALLACE: Uh-huh.

22 THE REPORTER: Sending it where?

23 MR. WALLACE: To me.

24 (The deposition concluded at 1:29 p.m.)

1 WITNESS CORRECTIONS AND SIGNATURE

2 Please indicate changes on this sheet of paper,
giving the change, page number, line number and reason
3 for the change. Please sign each page of changes.

4 PAGE/LINE CORRECTION REASON FOR CHANGE

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Anne Holland Wilson

1 S I G N A T U R E O F W I T N E S S

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10 STATE OF _____ *

11 COUNTY OF _____ *

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ANNE HOLLAND WILSON

Before me, _____, on
this day personally appeared ANNE HOLLAND WILSON, known
to me (or proved to me under oath or through
_____) (description of identity card
or other document) to be the person whose name is
subscribed to the foregoing instrument and acknowledged
to me that they executed the same for the purposes and
consideration therein expressed.

Given under my hand and seal of office
this _____ day of _____, 2016.

Notary Public in and for

the State of _____

1 COUNTY OF HARRIS)

2 STATE OF TEXAS)

3

4 REPORTER'S CERTIFICATE

5

6 I, KERRIENNE L. BOND, Certified Shorthand Reporter
7 in and for the State of Texas, hereby certify that this
8 transcript is a true record of the testimony given by
9 the witness named herein, after said witness was duly
10 sworn by me.

11 I further certify that I am neither attorney nor
12 counsel for, related to, nor employed by any of the
13 parties to the action in which this testimony was taken.
14 Further, I am not a relative or employee of any attorney
15 of record in this cause, nor do I have a financial
16 interest in the action.

17 Certified to by me this 24th day of March 2016.

18

19

20

21 _____
KERRIENNE L. BOND, TEXAS CSR NO. 8537

Expiration Date: 12-31-16

22 Golkow Technologies, Inc.

877-370-3377

23 (713) 583-2442 (FAX)

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